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Program Evaluation and Assessment Scheme (PEAS)

Developed as part of a cooperative agreement
Between
Health Resources and Services Administration
Maternal and Child Health Bureau,
Genetic Services Branch
and
National Newborn Screening and Genetics Resource Center
Department of Pediatrics
The University of Texas Health Science Center at San Antonio

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Introduction to PEAS

Of the approximately 4 million births annually in the United States, it is believed that essentially all undergo some form of newborn screening (NBS), but there is extreme variability in the way that screening occurs. In many programs, there is little or no emphasis placed on assessment and evaluation of the quality or functions of individual screening system components, or the system as a unit, unless or until an obvious problem is encountered. While financial resources, time and personnel play a role as to why programs do not spend much time on assessment and evaluation, the lack of national consistency between programs and the lack of well thought out models for reviewing system quality also play a role.

NBS is a system composed of six component parts: education, screening, follow-up, diagnosis, management, and evaluation. It may be viewed more simplistically as a pre-analytic, analytic, and post-analytic system in which laboratory analysis is preceded by pre-analytic education and specimen collection/submission and followed by post-analytic follow-up, diagnosis, education/counseling, intervention and outcome evaluation. This Program Evaluation and Assessment Scheme (PEAS) provides a uniform set of questions that can be used as a self-assessment tool in evaluating the way in which the various parts of individual screening systems function. In written form, references are provided for review when assessment of a particular item indicates the need for change. A more interactive version of the PEAS is planned using Internet and other computerized options.

The PEAS components were developed by working groups comprised of newborn screening stakeholders from consumer advocacy groups, birthing facilities, community organizations, newborn screening programs and federal support agencies. Throughout the PEAS, the user will find terms that may appear to be nonspecific, such as 'timely,' 'periodic,' and others. These terms were used intentionally to provide flexibility within programs for determining specific evaluation parameters. They were not intended to be used in a permissive way, but instead were intended to draw attention to a need for more precise definitions on the part of the program. Where national standards or consensus exists, more definitive terms are used. Items that are highlighted in gray ( ) are items that provide a means of quantitatively or qualitatively measuring performance. As standardization evolves, the PEAS will be modified to reflect more precise values for expected ranges of quality indicators.

Recognizing that the newborn screening program serves as the administrative part of the larger screening system, program administrators are encouraged to use the PEAS to refine and enhance all of the system components. Because of the variety of ways in which newborn screening system specifics are implemented across the country, it is not possible to identify a 'best' way to use the PEAS. There are many technical questions within the PEAS, and therefore it is unlikely that a single person can adequately assess all parts of the system. It is suggested that a person with laboratory expertise address the issues related to laboratory and a person with program administrative/follow-up/education expertise address the non-laboratory issues. There are, of course, some issues that will apply to both.

Comments and suggestions for improvements should be submitted to Dr. Brad Therrell, National Newborn Screening and Genetics Resource Center, 1912 W. Anderson Ln. #210, Austin, Texas 78757, e-mail: Therrell@uthscsa.edu.

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NEWBORN SCREENING PERFORMANCE EVALUATION AND ASSESSMENT

CHECKLIST FOR NEWBORN SCREENING SYSTEM PERFORMANCE WITH REFERENCES FOR SELF-HELP

I. GENERAL NEWBORN SCREENING SYSTEM CONSIDERATIONS

A. EDUCATION PLAN - Education is an essential element of the newborn screening system that must be present throughout. While educational activities exist in each of the three areas of screening activities (pre-analytical, analytical, and post-analytical), a comprehensive SMART (specific, measurable, achievable, realistic, time-bound - SMART) plan must exist so that education is implemented, utilized, and maintained throughout the system to meet the needs of public heath professionals, health care providers, consumers, and policy-makers.

PERFORMANCE INDICATOR	FINDINGS Yes	No	In Progress	REFERENCES
Education plan:				
a. A comprehensive, written education plan prepared with input from representative stakeholders exists.	☐	☐	☐	1,2,3
b. The comprehensive education plan provides information for:				
i. Public health professionals.	☐	☐	☐	1
ii. Health care providers.	☐	☐	☐	1
iii. Birthing facility staff working with newborn screens.	☐	☐	☐	1
iv. Consumers (Parents).	☐	☐	☐	1,4,5
v. Policy-makers.	☐	☐	☐	1
c. The comprehensive education plan includes:				
i. A mission statement.	☐	☐	☐	2,6,7,8
ii. Defined goals and objectives.	☐	☐	☐	2
iii. A means for obtaining input from stakeholders receiving the education.	☐	☐	☐	2
iv. A description of personnel necessary to administer all aspects of the plan.	☐	☐	☐	2
v. Action steps to address the needs of each target audience.	☐	☐	☐	2
vi. Diverse modes of education (Internet, in-service, etc.).	☐	☐	☐	6
vii. A method for evaluating and ensuring cultural appropriateness.	☐	☐	☐	9,10
viii. A method for evaluating and ensuring appropriate literacy level.	☐	☐	☐	9
ix. Methods for disseminating materials to target audiences.	☐	☐	☐	6
x. A method for periodic review and update of the plan.	☐	☐	☐	2,11

d. The education plan (see previous bullet) is reviewed annually by newborn screening program administrators and advisory committee members to assess its usefulness, its impact, and its relevance to current program activities, with updates asappropriate. ☐ ☐ ☐ _____

B. **COMPUTERIZED INFORMATION SYSTEM - A c**omputerized information system is essential for managing the patient information that begins at the time of birth and continues throughout life. While newborn screening systems are particularly interested in limited information sufficient to identify and manage their associated newborn screening information, the ability of the system to interact or integrate with other systems is a critical consideration. Data linkages should take advantage of related systems with similar data needs so that the time, effort, and errors that can occur in a duplicative process are avoided. In particular, data linkages to vital records, immunization records, birth defects registries, Women Infants and Children Program (WIC), Children With Special Health Care Needs Program (CSHCN), and lead poisoning prevention program are examples of child health data systems accessing similar demographic information. Linkages to systems that utilize program data for evaluation of systems' effects should also exist – Title V, National Newborn Screening Information System, etc.

PERFORMANCE INDICATOR	FINDINGS Yes	No	In Progress	REFERENCES
1. Scope:				
a. A comprehensive, written, HIPAA compliant informatics plan is available, developed with input from representative stakeholders	☐	☐	☐	12,13
b. The ultimate information system goal is comprehensive health data (child health profile) access at the medical home.	☐	☐	☐	14
c. The ability exists (or ongoing efforts) to link newborn screening heelstick data with other data systems.	☐	☐	☐	15, 15a
d. Data linkages between dried blood spot screening and other appropriate health information systems are a continuing consideration (e.g. representative on agency public health informatics planning committee).	☐	☐	☐	15,16,22
e. Newborn heelstick screening data linkages exist through database linkages with programs such as:				
i. Vital records (e.g. births, deaths)	☐	☐	☐	15,17,18,19
ii. Newborn hearing screening	☐	☐	☐	15,17,18,19
iii. Immunizations	☐	☐	☐	15,17,18,19
iv. CSHCN (Children with Special Health Care Needs)	☐	☐	☐	15,17,18,19
v. Others (Lead, Birth Defects, WIC, Part C, etc.)	☐	☐	☐	15,17,18,19
f. Inclusion of a data field for the newborn screening serial number (filter paper collection device/card) compliant with the CLSI/NCCLS recommended format (or other equivalent unique identifier) exists.	☐	☐	☐	15.20,21,23
g. Security levels and procedures for computer access are defined and enforced.	☐	☐	☐	24,26,27,28
h. The newborn screening information system provides for:				
i. Capture/input of patient demographic information.	☐	☐	☐	15,29
ii. Capture/input of screening laboratory test results.	☐	☐	☐	15,30,31
iii. Comprehensive and ongoing patient follow-up case management (including automated generation of 'reminder' notices to case manager).	☐	☐	☐	15.32,33
iv. Rapid notification of "out-of-range" test results to submitters, primary care physicians	☐	☐	☐	15,34,34b
v. Rapid notification of "invalid" test results to appropriate persons.	☐	☐	☐	34,34b

vi.	Rapid notification of 'in range' test results to appropriate persons.	☐	☐	☐	34,34b
vii.	Appropriate and accurate laboratory worklists.	☐	☐	☐	35,36
viii.	Creation/printing/transmittal of screening laboratory reports to submitters and primary care physicians.	☐	☐	☐	37
ix.	Editing/correcting reports (archived and/or printed).	☐	☐	☐	38,39
x.	A library of submitters with current address information.	☐	☐	☐	40
xi.	A library of subspecialists	☐	☐	☐	40
xii.	A library of treatment centers	☐	☐	☐	40
xiii.	Tracking of user access and edits.	☐	☐	☐	41,42
xiv.	Linking ability for multiple specimens on the same infant.	☐	☐	☐	43
xv.	User-friendly access to appropriate information for national data reporting.	☐	☐	☐	44
xvi.	Appropriate management reports for laboratory and follow-up managers.	☐	☐	☐	45,46
xvii.	Capability to link to birth records.	☐	☐	☐	47
xviii.	Capability to link to other public health infant medical data systems.	☐	☐	☐	47
xix.	Capability to accept and transmit select information to other external data systems such as the national data system or other electronic medical records	☐	☐	☐	48

2, <u>Integrity:</u>

a.	A comprehensive, written operations manual exists.	☐	☐	☐	49,50,51
	i. Documentation of an annual review/update of the manual exists.	☐	☐	☐	51,52
	ii. A data system quality assurance plan is included in the manual.	☐	☐	☐	52,53
b.	Data are maintained in an acceptable, standardized format that complies with established national data standards.	☐	☐	☐	54,55
c.	A system back-up plan exists such that data are not at risk for loss due to an unexpected emergency.	☐	☐	☐	55,56,57,58
d.	Records documenting data back-up activities are maintained.	☐	☐	☐	59
e.	The data system includes appropriate security measures that protect the privacy of the data in the system.	☐	☐	☐	60
f.	Technical support for computer problems is readily available.	☐	☐	☐	57,61,62,63
g.	A system maintenance plan exists	☐	☐	☐	63
h.	Appropriate system hardware maintenance is documented.	☐	☐	☐	63
i.	Appropriate system software maintenance (updates) is documented.	☐	☐	☐	63
j.	Where system integration exists, documented quality assurance procedures are in place to ensure data integrity.	☐	☐	☐	
k.	The computer environment (including facility) is conducive to maintaining confidential records.	☐	☐	☐	64,65
l.	There is a written policy/procedure that ensures confidentiality of patient demographic information.	☐	☐	☐	24,25,64,65
m.	There is a written policy/procedure ensuring confidentiality of patient test results.	☐	☐	☐	25,64
n.	Safeguards are in place to preclude unauthorized computer access.	☐	☐	☐	24,60,64
o.	Computer security precludes unauthorized data entry (including release of results)	☐	☐	☐	64,66
p.	Procedures exist for validating timeliness, accuracy and completeness of all data entry.	☐	☐	☐	
q.	There is a defined procedure for verifying that computer-generated laboratory data reports are accurate	☐	☐	☐	68,69,70,71

(i.e. that computer data are the same as manual calculations).

r.	There is a procedure for verifying that calculation formulas used by an automated system for calculating patient results are correct before reporting results.	☐	☐	☐	69,71
s.	A procedure is in place for verifying that data transferred from a laboratory instrument and reported by an automated reporting system are identical.	☐	☐	☐	68,72
t.	There is a procedure for correcting/documenting inaccurate data generated by a computerized reporting system.	☐	☐	☐	38,73

C. MONITORING OF TIMELY AND UNIVERSAL SCREENING. In order for the newborn screening system to achieve the goal of early identification and intervention for affected newborns, a system must exist to ascertain the screening status of all newborns within the screening jurisdiction. This system must include linkage between birth certificates and newborn screening records. It must also include appropriate linkages between public and private screening systems.

	PERFORMANCE INDICATOR	FINDINGS Yes	No	In Progress	REFERENCES
1.	**Initial Screening:**				
a.	Assignment of responsibility for ensuring that initial newborn screening occurs is clearly defined either in law or rule, including births occurring outside of recognized birthing facilities (e.g. home births).	☐	☐	☐	
b.	Compliance with requirements for newborn screening is periodically audited by comparing birth records to newborn screening records.	☐	☐	☐	74,75
c.	Compliance monitoring includes newborns born:				
i.	In federal facilities contracting elsewhere for screening services (e.g. military, Indian reservations).	☐	☐	☐	76
ii.	Outside of recognized birthing facilities. (e.g. at home).	☐	☐	☐	76
iii.	In one facility, but transferred to another facility (including transfers across jurisdictional boundaries).	☐	☐	☐	76
iv.	In a facility receiving services through other than the officially designated screening laboratory(ies).	☐	☐	☐	76
d.	In cases where refusal of required testing occurs, a process is in place to document and report such refusals.	☐	☐	☐	78
e.	Numbers and reasons for testing refusals are periodically reviewed to determine whether there are trends in refusals that require further investigation and action.	☐	☐	☐	76
2.	**Subsequent Screens:**				
a.	Assignment of responsibility for ensuring that second or other repeat screening occurs is clearly defined either in law or rule, including births occurring outside of recognized birthing facilities (e.g. home births).	☐	☐	☐	74
b.	Compliance with requirements for newborn screening is periodically audited by comparing birth records and initial newborn screening records with subsequent newborn screening records.	☐	☐	☐	74
c.	A process exists for monitoring compliance with subsequent screening that may be necessary as a result of:				
i.	A universally required second screen.	☐	☐	☐	74
ii.	An initial test result requiring a second screen as a result of inconsistent or inconclusive testing results.	☐	☐	☐	74
iii.	An "invalid" initial screening test (eg. unsatisfactory or no specimen).	☐	☐	☐	74
d.	In cases where refusal of subsequent testing occurs, a process is in place to document and report such refusals.	☐	☐	☐	74

e.	Numbers and reasons for subsequent testing refusals are periodically reviewed to determine whether there are trends in refusals that require further investigation and action.	☐	☐	☐	74

D. PROGRAM ADMINISTRATION AND FINANCING - In order for the newborn screening system to function, there are critical administrative and financial issues that must be addressed such as adequate newborn screening program staffing, system oversight capacity, and involvement of stakeholders in addressing system needs. Financing and administrative considerations must comprehensively address system needs for future growth.

	PERFORMANCE INDICATOR	FINDINGS Yes	No	In Progress	REFERENCES
1.	**Administration:**				
a.	Policies and procedures exist that govern program administration.	☐	☐	☐	77,79,80
b.	A comprehensive communication plan exists that includes active communication and public relations efforts to disseminate program information.	☐	☐	☐	13
c.	Updated program personnel contact details (names and telephone information) are available to consumers.	☐	☐	☐	1,3,6
d.	Updated program personnel contact details (names and telephone information) are available to health care providers.	☐	☐	☐	1,3,6
e.	Information dissemination targets within the plan include:				
	i. The general public.	☐	☐	☐	1,3,6
	ii. Parents and grandparents.	☐	☐	☐	1,3,6
	iii. Health professionals involved in newborn screening.	☐	☐	☐	1,3,6
	iv. Health professionals with limited involvement in newborn screening.	☐	☐	☐	1,3,6
	v. Policy makers and legislators.	☐	☐	☐	1,3,6
f.	Maintain a capacity for disseminating program updates that include:				
	i. Active and updated website.	☐	☐	☐	8,10,84
	ii. Periodic newsletter widely disseminated.	☐	☐	☐	8,10,84
	iii. Annual report of program statistics.	☐	☐	☐	8,10,84
g.	Copies of all pertinent laws, rules and regulations are readily accessible within the program and are available to stakeholders.	☐	☐	☐	81,82,85
h.	An organizational chart defining administrative relationships is readily accessible within the program	☐	☐	☐	2
i.	Descriptions of personnel roles and responsibilities are readily accessible.	☐	☐	☐	2
j.	Adequate and appropriate staff development activities are available.	☐	☐	☐	1
k.	There is a defined procedure for documenting personnel proficiency.	☐	☐	☐	2
l.	An external advisory committee exists.	☐	☐	☐	87
m.	The external advisory committee:				
	i. Is multi-disciplinary with wide representation from concerned stakeholders outside of the administrative agency (including parents of children affected by screened conditions, third party	☐	☐	☐	87

	payers, subspecialists, health care providers, etc.).				
ii.	Has a formal mission and operational guidelines.	☐	☐	☐	87
iii.	Meets on a regular basis (at least annually)	☐	☐	☐	87
iv.	Has a formalized process of decision-making	☐	☐	☐	87
v.	Has a formal process for providing advice and input into program operations	☐	☐	☐	87
vi.	Periodically reviews and evaluates program and national data as a means of program improvement and development.	☐	☐	☐	83,87
vii.	Provides appropriate program advocacy as needed.	☐	☐	☐	87
viii.	Publishes and widely distributes timely minutes of all meetings.	☐	☐	☐	87
n.	An internal advisory committee within the administrative agency exists that includes persons who have a role in, or are affected by, the newborn screening program.	☐	☐	☐	87
o.	The internal advisory committee (see previous bullet):				
i.	Meets periodically to address program issues for both laboratory and follow-up.	☐	☐	☐	87
ii.	Provides advice to program administrators on other issues of interest to the group.	☐	☐	☐	87
p.	A specific process exists (consistent with national recommendations) for determining which conditions should be included in the screening panel.	☐	☐	☐	90

2. <u>Financing:</u>

a.	A cost accounting process is in place that adheres to standard accounting procedures and documents <u>all</u> program costs.	☐	☐	☐	86,88,89,91,94
b.	A program finance/business plan is available that provides a comprehensive plan for a sustainable newborn screening system.	☐	☐	☐	86,88,89,91,94
c.	The financing plan adequately addresses:	☐	☐	☐	77
i.	Possible financing alternatives.	☐	☐	☐	77
ii.	Laboratory screening services.	☐	☐	☐	77
iii.	Comprehensive follow-up services.	☐	☐	☐	77
iv.	Comprehensive educational activities.	☐	☐	☐	77
v.	Confirmatory/diagnostic laboratory services.	☐	☐	☐	77
vi.	Confirmatory/diagnostic clinical services.	☐	☐	☐	77
vii.	Genetic counseling services.	☐	☐	☐	77
viii.	Nutritional counseling services.	☐	☐	☐	77
ix.	Subspecialty consultative services.	☐	☐	☐	77
x.	Employee continuing education.	☐	☐	☐	3
xi.	Employee recruitment and retention.	☐	☐	☐	77
xii.	A mechanism for assessing adequacy of payment for medical management	☐	☐	☐	77
xiii.	A mechanism for identifying and overcoming barriers to payment for medical management.	☐	☐	☐	77
xiv.	Public relations activities.	☐	☐	☐	77

xv.	Program/test development.	☐	☐	☐	77
xvi.	Data management.	☐	☐	☐	77
xvii.	Data integration.	☐	☐	☐	77
xviii.	Program evaluation activities (eg. short- and long-term outcome data).	☐	☐	☐	42
d.	Third party payers are included in decision-making processes related to financing.	☐	☐	☐	86
e.	Parents of affected newborns are provided with timely assistance in dealing with financial issues, including third-party reimbursement and other financial issues affecting the receipt of case-related medical services.	☐	☐	☐	86,94
f.	Where financial arrangements and contracts exist for program services, compliance indicators are defined and periodically monitored and evaluated.	☐	☐	☐	92,93

E. CONTINGENCY PLAN - Contingency planning is essential to ensure continuity of the newborn screening system in case of an emergency. The plan must include not only laboratory contingencies, but also contingencies for specimen collection and transport, record integrity, and follow-up/service activities.

PERFORMANCE INDICATOR		FINDINGS			REFERENCES
		Yes	No	In Progress	
1. Program Administration:					
a.	There is a comprehensive contingency plan for minimizing interruption of newborn screening systems operations in cases where an emergency may exist developed with input from representative internal/external stakeholders.	☐	☐	☐	100,101,102
b.	The contingency plan includes:				
i.	A chain of authority to operationalize the plan and alternative notification processes for initiating the contacts necessary for implementation (i.e. strategies for overcoming compromised communications).	☐	☐	☐	105
ii.	A system for ensuring that all administrative records are appropriately protected and maintained.	☐	☐	☐	101,102
c.	There is documentation that the contingency plan has been periodically reviewed and tested.	☐	☐	☐	101,102,103
2. Laboratory:					
a.	There is a comprehensive contingency plan for minimizing interruption of laboratory operations in cases where an emergency situation affects continued laboratory operation/service.	☐	☐	☐	100,104
b.	The contingency plan includes:				
i.	A chain of authority to operationalize the plan and alternative notification processes for initiating the contacts necessary for implementation (i.e. strategies for overcoming compromised communications).	☐	☐	☐	105
ii.	A system for ensuring that all laboratory records are appropriately protected and maintained.	☐	☐	☐	105
c.	There is documentation that the contingency plan has been periodically reviewed and tested.	☐	☐	☐	103
3. Follow-up:					
a.	There is a comprehensive contingency plan for minimizing interruption of follow-up operations and continuation of follow-up services (including diagnostic need) in cases where an emergency disrupts rapid and continuous	☐	☐	☐	100,101,102

program activities.

b. The contingency plan includes:

i. A chain of authority to operationalize the plan and alternative notification processes for initiating the contacts necessary for implementation (i.e. strategies for overcoming compromised communications).	☐	☐	☐	105
ii. Strategies to meet the needs of families being followed by the newborn screening program to avoid disruption of needed medical services such as access to medical formulas and foods, and medications.	☐	☐	☐	101,102
iii. A system for ensuring that all follow-up records are appropriately protected and maintained.	☐	☐	☐	101,102
iv. A method for ensuring that all newborns needing screening are screened.	☐	☐	☐	101,102
v. A method for ensuring that all screened newborns receive laboratory test results and needed follow-up.	☐	☐	☐	101,102
c. There is documentation that the contingency plan has been periodically reviewed and tested.	☐	☐	☐	101,102,103

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II. PRE-ANALYTICAL CONSIDERATIONS

A. PERSONNEL - Employee training must ensure qualified personnel for the appropriate tasks in the newborn screening laboratory and for follow-up activities. A comprehensive employee training program must exist and include new employee orientation, staff development, and performance assessment activities aimed at achieving a proficient workforce. A system for updating employee knowledge should exist along with a plan for cross-training wherever possible. Recruitment and retention of qualified workers should be a priority.

PERFORMANCE INDICATOR	FINDINGS Yes	No	In Progress	REFERENCES
1. Personnel Training, Recruitment and Retention:				
a. A personnel training plan/program exists.	☐	☐	☐	1
b. Sufficient staff are available to administer the program.	☐	☐	☐	1
c. The training plan for new personnel includes (in writing) instruction in:				
i. Administrative policies and procedures.	☐	☐	☐	2,3
ii. Program operation (including all systems components).	☐	☐	☐	2,3
iii. Safety.	☐	☐	☐	4
iv. Technical procedures (as appropriate).	☐	☐	☐	1
v. Available resources (local, regional, national, international).	☐	☐	☐	2,3
d. Employee competency is assessed and approved prior to independent work assignments.	☐	☐	☐	5,6
e. Policies define continued training expectations for all employees.	☐	☐	☐	7
f. Updated training is documented.	☐	☐	☐	4
g. A plan for cross-training personnel is present.	☐	☐	☐	8
h. Cross-training activities are documented.	☐	☐	☐	8
i. A plan for retaining good personnel exists.	☐	☐	☐	8
j. Staff turnover is periodically monitored to assess the success of recruitment and retention efforts.	☐	☐	☐	
k. There is a process in place to obtain feedback from personnel (managers and trainees) concerning the training program.	☐	☐	☐	
2. Personnel Competency:				
a. A written procedure, compatible with pertinent licensure requirements, is present to assess and document personnel competency.	☐	☐	☐	7,9,10
b. Competency assessment includes:				
i. Documentation of sufficient educational background (e.g. transcript, copy of diploma).	☐	☐	☐	13,14
ii. Documentation of appropriate experience.	☐	☐	☐	13,14
iii. Documentation of continuing education/certification.	☐	☐	☐	15,16

iv.	Written procedures for actions to be taken when competency is deemed unacceptable	☐	☐	☐	7,9,17
v.	Appropriate performance on proficiency testing or other quality performance measures (laboratory personnel).	☐	☐	☐	13
vi.	An annual assessment of technical competency using quantitative or semi-quantitative measures (laboratory personnel - compliant with CLIA/CAP requirements).	☐	☐	☐	7,15
c.	Performance competency is evaluated as least annually for each employee.	☐	☐	☐	11,12

B. PRENATAL EDUCATION - Education of parents and health professionals prior to the birth of the newborn provides the optimal mechanism for delivering useful information about the screening process. Materials should be available in a variety of formats and must meet the needs of the intended audience. They must be consistent with the general education plan and evaluated accordingly.

PERFORMANCE INDICATOR		FINDINGS			REFERENCES
		Yes	No	In Progress	
1. <u>Preparation/Distribution of PARENT Education Materials:</u>					
a.	The parent educational materials about newborn screening:				
i.	Adhere to the written educational plan.	☐	☐	☐	18,19,20
ii.	Are accurate (as determined by appropriate subspecialty and/or other advisors).	☐	☐	☐	19,20
iii.	Are current (reviewed/updated at least annually).	☐	☐	☐	19,20
iv.	Are brief, concise, and easy to understand (as determined by parent users).	☐	☐	☐	19,20
v.	Are available in a variety of formats (e.g. brochure, video, lay publications, website, etc.).	☐	☐	☐	21
vi.	Are sensitive to cultural issues (as determined by appropriate advisors).	☐	☐	☐	22,23,24
vii.	Meet appropriate literacy standards (at least 5th grade or lower readability).	☐	☐	☐	25,26,27,28
viii.	Are attractive and eye catching (as determined by parent users).	☐	☐	☐	29,30
ix.	Meet their intended use (i.e. evaluated for impact by periodically assessing user knowledge).	☐	☐	☐	31
x.	Are free of charge.	☐	☐	☐	30
xi.	Are available in appropriate languages.	☐	☐	☐	30
b.	There is a procedure in place for systematically reviewing and updating the parent educational materials.	☐	☐	☐	31,32,33
c.	Educational materials are distributed, as part of the educational plan, to appropriate prenatal care providers including:	☐	☐	☐	32,33,34
i.	Obstetrics providers.	☐	☐	☐	32,33,34
ii.	Birthing facilities.	☐	☐	☐	32,33,34
iii.	Mid-wives.	☐	☐	☐	32,33,34
iv.	Family physicians.	☐	☐	☐	32,33,34
v.	Pediatricians.	☐	☐	☐	32,33,34
vi.	Pre-natal class instructors.	☐	☐	☐	32,33,34
vii.	Parents.	☐	☐	☐	32,33,34

d.	Usage patterns are monitored and distribution adjustments made if needed.	☐	☐	☐	31
e.	Periodic assessment of availability occurs through random checks of distribution sites.	☐	☐	☐	
f.	Educational materials distributed by others (hospitals, support groups, etc.) are reviewed for accuracy and and appropriateness to ensure that they do not conflict with program information.	☐	☐	☐	30

2. <u>Preparation/Distribution of PROFESSIONAL Education Materials:</u>

a.	The professional educational materials about newborn screening:				
	i. Adhere to the written educational plan.	☐	☐	☐	34
	ii. Are accurate (as determined by appropriate subspecialty and/or other advisors).	☐	☐	☐	32
	iii. Are current (reviewed and updated at least annually).	☐	☐	☐	32
	iv. Reflect national standards of practice, where national standards exist.	☐	☐	☐	32,36
	v. Are designed to meet the needs of the target audience (as determined by professionals using the materials).	☐	☐	☐	31
	vi. Are evaluated for impact by periodically assessing knowledge of users.	☐	☐	☐	31
b.	There is a procedure in place for systematically reviewing and updating the professional educational materials.	☐	☐	☐	31
c.	Materials are distributed appropriately according to the education plan.	☐	☐	☐	32
d.	Usage patterns are monitored and distribution adjustments made if needed.	☐	☐	☐	31
e.	Periodic assessment of availability occurs through random checks of distribution sites.	☐	☐	☐	

C. Screening Process - Proper specimen collection and information handling are essential to the screening process. Heelstick blood collection should be performed according to most current CLSI/NCCLS Standard. The blood collection device should meet the performance standards specified in the CLSI/NCCLS Standard. Patient data/demographic information placed on the collection device should be complete, accurate and legible and the patient's identity should be confirmed at the time of specimen collection. Many of the conditions in newborn screening require immediate diagnosis and treatment, and some of the testing procedures may be negatively affected by specimen collection/transport delays. Thus, the screening process must proceed quickly, accurately and efficiently in order to provide the greatest benefit.

	PERFORMANCE INDICATOR	FINDINGS Yes	No	In Progress	REFERENCES
1. <u>Specimen Collection Device</u>					
a.	There is a written protocol for assessing overall compliance of the blood collection device/card that complies with the latest CLSI/NCCLS Standard.	☐	☐	☐	37,38,39,40,41
b.	For the filter paper portion of the printed collection card/device, there is documentation that appropriate quality indicators comply with the program's defined acceptance standards.	☐	☐	☐	37-39,41-43
c.	For the printed portion of the printed collection card/device, there is documentation that appropriate quality indicators comply with the program's defined acceptance standards.	☐	☐	☐	41,43,44
d.	Indication of "Compliance with CLSI/NCCLS Standard" is printed on the blood collection device/card if all elements of the standard are met.	☐	☐	☐	44
e.	The expiration date of the specimen collection device/card is printed on the device/card.	☐	☐	☐	45,46

f.	Periodic checks of incoming cards document that 'out-of-date' devices/cards are not in use.	☐	☐	☐	
g.	A unique serial number compliant with CLSI/NCCLS recommended format (or other acceptable unique number) is included on the printed collection device/card.	☐	☐	☐	45,47,48,49
h.	Distribution of the blood collection devices/cards includes an inventory control system that links serial numbers to submitters.	☐	☐	☐	47
i.	There is a procedure for specimen submitters to receive immediate replacement of defective/outdated collection devices/cards.	☐	☐	☐	50

2. Specimen Collection/Transmittal

a.	Written specimen collection procedures exist consistent with latest CLSI/NCCLS standard for blood collection on filter paper for newborn screening programs.	☐	☐	☐	48,51-62
b.	A description of the steps to be taken relative to specimen transport is included in the procedure describing specimen collection.	☐	☐	☐	63,64
c.	A plan exists for update/training of birthing facility personnel responsible for newborn screening specimen collection and submission (nurses, clerks, phlebotomists, etc.).	☐	☐	☐	65,66,67,68
d.	The training plan includes physicians/nurses/mid-wives/laboratory staff who may be collecting and submitting specimens.	☐	☐	☐	68
e.	There is a timely and active process for educating all persons who collect heelstick specimens.	☐	☐	☐	65,66,67
f.	The following items are included in the educational process:				
	i. Confirming that baby's name matches the name on the specimen collection device/card.	☐	☐	☐	29,69,70
	ii. Ensuring completeness, accuracy and legibility of patient information.	☐	☐	☐	48,71,72,73
	iii. Collecting the heelstick specimen.	☐	☐	☐	52-56
	iv. Monitoring and ensuring specimen acceptability at time of collection	☐	☐	☐	71,74,75
	v. Proper procedure for drying blood spots prior to shipment.	☐	☐	☐	76,77
	vi. The need for documenting date and time of specimen shipment (particularly when courier services are Used).	☐	☐	☐	78
	vii. An evaluation process to assess knowledge gained by participants.	☐	☐	☐	
g.	Where parent/guardian refusal can occur, a standardized refusal procedure is in place (with legal approval).	☐	☐	☐	65
h.	Documentation of testing refusal occurs according to screening program guidelines	☐	☐	☐	65
i.	A periodic review of numbers and reasons for refusing testing occurs to assess possible program changes.	☐	☐	☐	

3. Specimen Receipt

a.	There is an operational system at the screening laboratory for documenting:				
	i. Date of specimen receipt.	☐	☐	☐	78,79,80
	ii. Time of specimen receipt.	☐	☐	☐	79,80,81
	iii. "Invalid" specimens - including reason "invalid".	☐	☐	☐	79,82,83
b.	The laboratory quality assurance plan includes criteria for evaluating the specimen's acceptability for analysis	☐	☐	☐	41,74,79,85

	at the time of laboratory receipt and check-in.				
c.	The defined specimen acceptability criteria include:				
	i. Quality indicators (e.g. no serum rings, no clots, etc.).	☐	☐	☐	41,74,79,85
	ii. Analytical acceptability criteria regarding quantity of specimen.	☐	☐	☐	41,83
	iii. Legibility of accompanying patient information.	☐	☐	☐	41,48,72
	iv. Completeness of accompanying patient information.	☐	☐	☐	85,86
	v. Accuracy of the accompanying patient information (dates, etc.).	☐	☐	☐	87-91
	vi. Age of specimen.	☐	☐	☐	41,91
d.	There is a written procedure for rapid submitter notification of "invalid" (unsatisfactory) specimens in addition to routine notification with a written (or electronic) laboratory report.	☐	☐	☐	83,92
e.	There is a written procedure for electronically entering (capturing) patient/specimen information.	☐	☐	☐	93,94,95
f.	All information electronically captured are evaluated for correctness of data entry (where all data fields cannot be monitored for staffing reasons, critical fields should be defined and their data quality monitored - methods included double entry or manual comparative checks).	☐	☐	☐	93-97
g.	Where present, a unique specimen identifier is captured by a method that avoids typographical errors (bar code, check sum character, double entry, etc.)	☐	☐	☐	45,98,99
h.	Error rates for electronic data entry are tracked and used to assess performance improvement.	☐	☐	☐	95,100,101
i.	There is a training plan for correcting poor data entry performance.	☐	☐	☐	102
j.	There is a process for updating missing critical data.	☐	☐	☐	103,104
k.	If data correction is allowed, there is a procedure for assuring that testing and reporting are not delayed while missing data are obtained.	☐	☐	☐	85,105
l.	Number of "invalid" specimens for each submitter are tracked daily including number of, and reasons for, "invalid" specimens in order to decrease the number of "invalid" specimens (goal defined by program, generally <0.5%).	☐	☐	☐	9,67,86
m.	Number of invalid data fields per specimen data form are tracked daily including number of blank fields and obvious errors in order to decrease the number of data errors (goal defined by program, generally <1 per form)	☐	☐	☐	78,84,102
n.	Specimen submitters are periodically notified of their ongoing performance in submitting acceptable (valid) patient information.	☐	☐	☐	78,102
o.	There is a written procedure for improving submitter performance relative to quality of specimens submitted.	☐	☐	☐	9,78,102
p.	There is a written procedure for improving submitter performance relative to quality of the patient information submitted.	☐	☐	☐	9,102
q.	There is a system for documenting date, contacted person, and person contacting as part of the process for tracking the actions performed for "invalid" specimens	☐	☐	☐	84
r.	There is a system for uniquely identifying specimens for laboratory tracking.	☐	☐	☐	45,107,108,109
s.	Specimens are processed over time periods that comply with written procedures designed to optimize patient benefits (generally within 24 hours or specimen receipt).	☐	☐	☐	79,84
t.	Periodic audits are documented that assess the processing time and document any necessary corrective actions.	☐	☐	☐	79,84
u.	Where specimens are shared between different laboratories as part of the screening process, there is a written protocol for ensuring that specimens are handled so that analytical data are appropriately matched for each specimen.	☐	☐	☐	79,110

v.	Where specimens are shared between different laboratories as part of the screening process, there are daily audits to ensure that specimens are received and analyzed in all laboratories involved.	☐	☐	☐	79,110

4. Specimen Tracking

a.	A specimen tracking quality assurance plan exists to ensure that procedures for specimen submission to the screening laboratory are properly followed.	☐	☐	☐	65,75,100,102
b.	There is a time for acceptable specimen transmittal that is defined as part of the specimen tracking quality assurance plan (transmittal within 1 day is ideal; within 2-3 days is generally acceptable).	☐	☐	☐	9,65,94,102
c.	There is an audit mechanism for monitoring specimen transmittal times included in the specimen tracking quality assurance plan (audit should occur at least annually; preferably quarterly).	☐	☐	☐	78,94,102
d.	There is a procedure for periodically (at least annually) assessing and notifying specimen submitters of their ongoing performance in timely submittal of specimens.	☐	☐	☐	78,84,94,102
e.	There is a written procedure for corrective actions when a submitter is identified with a problem relative to timely specimen submittal.	☐	☐	☐	67,102,111,112
f.	A specimen tracking system is in place in each birthing facility (usually includes nursery and facility laboratory) documenting:				
	i. That every newborn is screened or offered screening (depending on local laws).	☐	☐	☐	68,73,113,114
	ii. If refusal of screening has occurred [date, person(s) refusing] (where allowed).	☐	☐	☐	65
	iii. The reason(s) for refusal (if refusal occurred).	☐	☐	☐	65
	iv. That every newborn transferred <u>into</u> the facility has been screened.	☐	☐	☐	71,116
	v. That every newborn transferred <u>away from</u> the facility has been screened.	☐	☐	☐	68,116
	vi. That every intensive care newborn receives a screening test by age 7 days.	☐	☐	☐	68,113,116
	vii. That each specimen collected has been sent to the screening laboratory within 24 hours of collection.	☐	☐	☐	99,64,117
	viii. That a screening result has been received for each submitted specimen within 14 days.	☐	☐	☐	65,78,99,108
	ix. That screening results have been rapidly transmitted to newborn's care provider.	☐	☐	☐	65,99,108,117
	x. That appropriate documentation of screening and screening results are recorded in the patient's record.	☐	☐	☐	67,111
g.	Where a tracking system exists that can monitor specimen transport more efficiently (e.g. electronic data transmission from the submitter, electronic courier tracking), there is a process for utilizing the tracking system.	☐	☐	☐	67,111
h.	Where specimens are submitted separately from data as a result of an automated data system at the submitting facility, the specimen transmittal procedure assures:				
	i. Quality data entry at the birthing facility (data validation procedure).	☐	☐	☐	72,98,118
	ii. Timely data entry at the birthing facility.	☐	☐	☐	72,98
	iii. Documentation of data transmission to the screening laboratory.	☐	☐	☐	72,98
	iv. Documentation of data receipt at the screening laboratory.	☐	☐	☐	72,81,98
i.	Where a courier system is used for specimen transport, records exist documenting:				
	i. Which specimens were transported by the courier (i.e. specimen serial numbers).	☐	☐	☐	119
	ii. Date and time of courier pick-up at specimen collection facility.	☐	☐	☐	63,81
	iii. Date and time of courier drop-off at screening laboratory.	☐	☐	☐	81

j. A specimen tracking system is in place at the screening laboratory documenting:				
i. The receipt of each blood specimen.	☐	☐	☐	78,79,80,84
ii. Whether or not the specimen was analytically acceptable.	☐	☐	☐	57,65,120,121
iii. The reason(s) for any specimens deemed unacceptable.	☐	☐	☐	74,82,121

D. LABORATORY SAFETY - Employee safety is an essential component in the newborn screening laboratory. A comprehensive safety training program must exist and successful completion by employees must be documented. Safety training must be timely and a mechanism for periodic updating of safety knowledge for employees must exist.

PERFORMANCE INDICATOR	FINDINGS Yes	No	In Progress	REFERENCES
1. **Employee Training**:				
a. Safety training is provided for all laboratory employees.	☐	☐	☐	122
b. Training in precautions with bloodborne pathogens is provided for all employees.	☐	☐	☐	122,123,124,125
c. Training in precautions for using hazardous chemicals is provided for all employees.	☐	☐	☐	122,126,127,128
d. All safety training is documented and records maintained.	☐	☐	☐	123,129,130
e. Fire/bomb/natural disaster evacuation drills are conducted at least twice/year.	☐	☐	☐	131,132,133
f. First aid and CPR training is available annually.	☐	☐	☐	132
2. **Safety Program**				
a. A defined laboratory safety program exists.	☐	☐	☐	134
b. Safety oversight is the responsibility of a designated Safety Officer.	☐	☐	☐	135
c. Where staffing permits, an active Safety Committee exists.	☐	☐	☐	134
d. Comprehensive written safety procedures exist either as a separate manual or as a part of laboratory operations procedures	☐	☐	☐	134,136
e. Documented review of the safety procedures occurs at least annually by the Safety Officer and the Newborn Screening Laboratory Director.	☐	☐	☐	137,138
f. The written safety procedures include:				
i. Defined authority for safety oversight.	☐	☐	☐	135
ii. Defined awareness responsibilities for individual employees.	☐	☐	☐	135
iii. General laboratory safety requirements (including illness and accident prevention.	☐	☐	☐	122,139
iv. Emergency response procedures in case of employee illness.	☐	☐	☐	140,141,142
v. Emergency response procedures in cased of a laboratory accident.	☐	☐	☐	140,141,142
vi. Proper procedures for handling bloodborne pathogens.	☐	☐	☐	122,123
vii. Emergency responses in case of bloodborne pathogen exposure.	☐	☐	☐	137,143,144

viii.	Proper procedures for handling hazardous chemicals (chemical hygiene).	☐	☐	☐	122,126
ix.	Emergency responses in case of hazardous chemical exposure	☐	☐	☐	140,145
x.	Fire prevention/control.	☐	☐	☐	146,147
xi.	Emergency evacuation procedures for fire or other emergency.	☐	☐	☐	132,133,148
xii.	Usage procedures for eye washes.	☐	☐	☐	149
xiii.	Usage procedures for emergency showers.	☐	☐	☐	149
xiv.	Avoidance of electrical hazards.	☐	☐	☐	150,151
xv.	Emergency response in case of electrical shock.	☐	☐	☐	140,152
xvi.	Incident/accident reporting.	☐	☐	☐	140,152
g.	A comprehensive safety inspection occurs at least annually.	☐	☐	☐	134,153
h.	Periodic emergency evacuation drills occur at least twice annually.	☐	☐	☐	131
i.	Periodic reviews and staff discussions of all incidents/accidents are documented.	☐	☐	☐	140,152
j.	Updated Material Safety Data Sheets (MSDS) are readily accessible to all staff.	☐	☐	☐	154,155
k.	A written bloodborne pathogen exposure control plan exists.	☐	☐	☐	137,143
l.	The bloodborne exposure control plan is reviewed and updated annually.	☐	☐	☐	137,156
m.	Employees review the exposure plan at least annually (documented).	☐	☐	☐	137,157
n.	The exposure plan includes information on:				
i.	Program management.	☐	☐	☐	137
ii.	Employee responsibility.	☐	☐	☐	137
iii.	Universal precautions.	☐	☐	☐	158,159,160
iv.	Needles and sharp object injuries.	☐	☐	☐	140,161
v.	Work area restrictions.	☐	☐	☐	162,163
vi.	Specimens and specimen containers.	☐	☐	☐	164,165,166
vii.	Contaminated equipment.	☐	☐	☐	158,167,168
viii.	Personal protective equipment.	☐	☐	☐	169,170,171
ix.	Regulated waste disposal.	☐	☐	☐	172,173
x.	Housekeeping.	☐	☐	☐	174,175
xi.	Immunizations.	☐	☐	☐	176,177,178
xii.	Post-exposure evaluation and follow-up.	☐	☐	☐	137,179
xiii.	Posted labels and warning and identification signs.	☐	☐	☐	180,181
xiv.	Biological Safety Cabinets	☐	☐	☐	182
o.	The bloodborne pathogens exposure control plan is reviewed by the Safety Officer and the Newborn Screening Laboratory Director at least annually.	☐	☐	☐	137,138
p.	A written chemical safety plan exists.	☐	☐	☐	126,183,184,185
q.	The chemical safety plan is reviewed and updated annually.	☐	☐	☐	134,186
r.	Employees review chemical safety plan at least annually (documented).	☐	☐	☐	134
s.	The plan includes information on:				
i.	Safety showers - location and use.	☐	☐	☐	187

ii.	Safety eye washes - location and use.	☐	☐	☐	149
iii.	Material Safety Data Sheets (MSDS).	☐	☐	☐	154,155
iv.	Chemical storage - inventory procedure and storage precautions.	☐	☐	☐	188,189,190
v.	Reagent labeling.	☐	☐	☐	191,192,193
vi.	Accident prevention.	☐	☐	☐	139,194
vii.	Chemical waste removal and disposal.	☐	☐	☐	172,195,196
viii.	Housekeeping (restricted or designated access).	☐	☐	☐	174
ix.	Exposures, injuries and illnesses- immediate actions.	☐	☐	☐	140,145
x.	Medical consultations and examinations.	☐	☐	☐	126,197
xi.	Emergency Response	☐	☐	☐	132
t.	The chemical safety plan is reviewed by the Safety Officer and the Newborn Screening Laboratory Director at least annually.	☐	☐	☐	138,198

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III. ANALYTICAL CONSIDERATIONS

A. TESTING PROCESS - The testing processes must undergo rigorous quality checks in order to ensure accurate screening results. Up-to-date procedure manuals that meet the requirements of CLIA '88 are required, including relevant updates, and the laboratory must have a CLIA/CAP certificate for operation. There must be an overall quality assurance plan with defined corrective actions to be taken when quality control indicators detect problems. Testing must be accurate and precise, and testing must occur within a time period sufficient to accomplish the goal of early detection and treatment as a preventive measure. *(Note: All terms and definitions within this section are those used in CLIA'88.)*

PERFORMANCE INDICATOR	FINDINGS Yes	No	In Progress	REFERENCES
1. Procedures Manual:				
a. There is a CLIA compliant laboratory procedure's manual(s).	☐	☐	☐	1,2
b. The procedure's manual defines the process for establishing analytical ranges for the various screening tests.	☐	☐	☐	1,2
c. The procedure's manual(s) is updated as procedural changes occur.	☐	☐	☐	3
d. All procedural changes are appropriately documented with date and person changing.	☐	☐	☐	4
e. Discontinued procedures are archived with documentation of the date the procedure was begun, the date discontinued, and the person archiving.	☐	☐	☐	5
f. There is a documented review of the procedure's manual(s) by the laboratory technical supervisor at least annually.	☐	☐	☐	4
g. A working procedure's manual(s) is readily available to all technical personnel.	☐	☐	☐	1
h. There is a written course of emergency action to be taken if a test system fails.	☐	☐	☐	6
i. There is an accountability process that ensures that personnel follow the procedures included in the procedure's manual(s).	☐	☐	☐	1
2. Quality Assurance Program:				
a. There is a written quality assurance plan for the laboratory.	☐	☐	☐	2,7,8,9
b. There is a periodic review of the quality assurance plan.	☐	☐	☐	10,11
c. There is routine documentation and review of all quality assurance events.	☐	☐	☐	12,13
d. The quality assurance plan defines a quality control process in the laboratory.	☐	☐	☐	9,14
e. The quality assurance plan specifies a process for:				
i. Sharing quality assessment findings among staff members in order to resolve problems.	☐	☐	☐	11
ii. Reviewing the effectiveness of corrective actions taken with appropriate staff.	☐	☐	☐	11
iii. Preventing recurrence of identified problems.	☐	☐	☐	11,15
iv. Obtaining information to assess clinical validity of screening tests.	☐	☐	☐	9,16

v.	Comparing screening test results with confirmatory testing results and resolving any discrepancies.	☐	☐	☐	15,17
vi.	Documenting corrective actions for any discrepancies found.	☐	☐	☐	15,17
f.	The methods for using quality control materials specify:				
i.	The number, type and frequency of testing controls for each different analytical procedure.	☐	☐	☐	18,19,20
ii.	An identical analytical process for analysis of controls and patient's specimens.	☐	☐	☐	21,22,23
iii.	Acceptability criteria with corrective actions if a test system is "out of control."	☐	☐	☐	24,25
iv.	A protocol for detecting/correcting errors resulting from a test system failure.	☐	☐	☐	26
v.	A protocol for detecting/correcting errors caused by operator performance.	☐	☐	☐	26
vi.	Documentation of corrective actions in the event of error detection.	☐	☐	☐	26
g.	The use of control materials complies with CLIA '88 including:				
i.	A procedure for validating the concentration of control materials.	☐	☐	☐	2,27
ii.	A procedure for establishing acceptable accuracy limits for controls.	☐	☐	☐	28,29,30
iii.	A procedure for establishing acceptable precision limits for controls.	☐	☐	☐	29,30
iv.	A process for monitoring assay accuracy based on control results.	☐	☐	☐	14,29,31,32
v.	A process for monitoring assay precision based on control results.	☐	☐	☐	14,29,31,32
vi.	Documentation of corrective actions in the event of accuracy or precision noncompliance.	☐	☐	☐	14,29,31,32
h.	Validation of assay calibrators/standards complies with CLIA '88 including:				
i.	A process for validating calibrator/standard concentrations before routine use.	☐	☐	☐	13,33
ii.	A process for documenting all calibrator/standard validation activity.	☐	☐	☐	20,34
iii.	A process for actions to be taken when performance of controls indicates a deviation from the anticipated results.	☐	☐	☐	34
iv.	Criteria for establishing acceptable assay performance (linearity, CV, etc.)	☐	☐	☐	7,20
v.	A process for documenting acceptable assay performance.	☐	☐	☐	13
vi.	A process for action(s) when assay performance is unacceptable.	☐	☐	☐	2,20
vii.	Documentation of corrective actions when unacceptable assay performance is noted.	☐	☐	☐	2,20
i.	The use of commercial assay kits and kit components complies with CLIA '88 including:				
i.	A protocol for reagent kit validation (both accuracy and precision).	☐	☐	☐	30
ii.	Documentation of kit validation prior to routine use.	☐	☐	☐	30
iii.	Adherence to manufacturer's protocol and/or documentation of all deviations.	☐	☐	☐	30
iv.	Documenting acceptable kit performance indicators on a routine basis.	☐	☐	☐	35
v.	Where appropriate, validating/documenting proper instrument operation.	☐	☐	☐	31
vi.	Documenting comparative evaluations of new lots of kit components with lots currently in use.	☐	☐	☐	34
vii.	Validation/documentation of methodology for those kits not FDA approved.	☐	☐	☐	33
j.	There is a procedure for validating reagent performance including:				
i.	Comparison to stated precision/accuracy specifications (commercial reagents).	☐	☐	☐	36,37,38
ii.	Establishing performance specifications (prepared reagents).	☐	☐	☐	38,39
iii.	Documenting performance characteristics.	☐	☐	☐	38,40
k.	The laboratory satisfactorily participates in dried blood spot and other CLIA compliant, external proficiency	☐	☐	☐	1,42,43,44,45,46

	testing activities.				
l.	There is a comprehensive written procedure for handling analysis, review and reporting of proficiency testing results.	☐	☐	☐	2,47,48
m.	The analytical procedure for analyzing proficiency and patient specimens is identical.	☐	☐	☐	44,45,49,50,51
n.	To the extent possible, proficiency samples are run for each analyte in the laboratory.	☐	☐	☐	45,46
o.	Personnel who routinely perform testing test proficiency specimens.	☐	☐	☐	44,49,50
p.	Proficiency testing records are accessible on site for at least two years.	☐	☐	☐	51,52,53
q.	There is a written procedure for investigating, documenting and correcting problems identified as a result of unacceptable proficiency testing results.	☐	☐	☐	48,54,55
r.	There is documentation of appropriate review of proficiency testing results by the technical laboratory supervisor.	☐	☐	☐	50,56
s.	There is documentation of corrective actions taken in the event of a proficiency testing error.	☐	☐	☐	44,55,57

B. LABORATORY INSTRUMENTATION - Laboratory instruments must be properly calibrated and maintained in order to provide the highest quality testing. Proper and timely maintenance and calibration must be documented. Instrument calibration processes must be efficient, effective, and timely. A procedure should exist for linking specimen results to the instrument(s) used in cases where instrument operation is critical to the overall analytical process.

	PERFORMANCE INDICATOR	FINDINGS Yes	No	In Progress	REFERENCES
1.	**Instrument Operation:**				
a.	There is a written operations procedure defining proper instrument operation.	☐	☐	☐	2
b.	The operations manual follows manufacturer's guidelines, or validated alternative protocol(s), for instrument use.	☐	☐	☐	58,59
c.	Appropriate training is documented for all instrument operators.	☐	☐	☐	60
d.	Where available, appropriate security controls exist that limit instrument access to properly trained personnel.	☐	☐	☐	61
2.	**Quality Assurance**				
a.	Instrument operation's checks (calibration/calibration) comply with CLIA '88 and include written procedures for:				
i.	Instrument calibration.	☐	☐	☐	60,62
ii.	Validating proper instrument operation prior to use.	☐	☐	☐	63
iii.	Validating proper instrument operation during analytical runs.	☐	☐	☐	63
iv.	Documenting compliance with manufacturer's operations procedures.	☐	☐	☐	64,65
v.	Documenting routine preventive maintenance and repairs.	☐	☐	☐	65,66
vi.	Documenting corrective actions when operational problems are detected.	☐	☐	☐	65,67
vii.	Documenting appropriate competency of instrument operators.	☐	☐	☐	58,65
viii.	Documenting recalibration when necessary.	☐	☐	☐	58,65,67,68
ix.	Reverification of operational parameters when reagent lots change.	☐	☐	☐	69,70

x.	Reverification of operational parameters when control lots change.	☐	☐	☐	69,71
xi.	Reverification of operational parameters when critical parts are replaced.	☐	☐	☐	69,72
xii.	Reverification of operational parameters when control materials reflect unusual analytical trends or shifts.	☐	☐	☐	69,73
xiii.	Reverification of operational parameters when instrument is moved.	☐	☐	☐	62,69
xiv.	Documentation of any reverification activities.	☐	☐	☐	62
b.	There are written maintenance protocols to ensure accurate and reliable testing performance of all laboratory instrumentation.	☐	☐	☐	38,66,74
c.	Manufacturer's guidelines for proper maintenance are followed.	☐	☐	☐	66,75
d.	Scheduled maintenance is performed with at least the frequency specified by the manufacturer.	☐	☐	☐	66,75
e.	The prescribed maintenance is documented for all laboratory equipment (including ancillary equipment such as incubators, centrifuges, refrigerators, etc.).	☐	☐	☐	66,75
f.	Corrective actions relative to functional problems are documented and include supervisory review.	☐	☐	☐	66,75

C. LABORATORYSUPPLIES/REAGENTS - Supplies/reagents must be of appropriate quality to provide analytical integrity. Procedures must exist for assuring that supplies/reagents are fresh. Reagent concentrations should be validated prior to use with patient specimens. Records of lot numbers of date-sensitive reagents and supplies should exist and be linked to specimens analyzed.

PERFORMANCE INDICATOR		FINDINGS			REFERENCES
		Yes	No	In Progress	
1. Quantity:					
a.	There are updated inventory records of the status of all consumable supplies.	☐	☐	☐	76
b.	There are written procedures defining minimum inventory levels for all laboratory consumables.	☐	☐	☐	77
c.	Sources for consumable are given in the laboratory operation's manual.	☐	☐	☐	3,38
d.	Inventory is rotated to optimize use of materials with shorter expiration dates.	☐	☐	☐	78
e.	The shelf life of consumables is included in inventory considerations.	☐	☐	☐	79
f.	A periodic audit of consumables is performed to validate inventory records and supply use.	☐	☐	☐	79
2. Quality					
a.	Supplies and reagents are stored according to manufacturer's recommendations.	☐	☐	☐	80
b.	Records of received consumable include date received, lot number and expiration date.	☐	☐	☐	38,80
c.	Reagent containers are properly labeled with:				
i.	Identification of contents.	☐	☐	☐	79
ii.	Concentration.	☐	☐	☐	79
iii.	Storage requirements.	☐	☐	☐	79

iv.	Preparation Date.	☐	☐	☐	79
v.	Expiration date.	☐	☐	☐	79
vi.	Preparer's initials.	☐	☐	☐	79
vii.	Lot number (if available).	☐	☐	☐	79
d.	There is appropriate documentation of safe disposal of expired reagents/supplies.	☐	☐	☐	81
e.	There is documentation of periodic inspections/corrective actions to ensure compliance with labeling and storage condition requirements.	☐	☐	☐	

D. WORKING ENVIRONMENT - Laboratory environmental conditions (e.g. temperature, humidity, etc.) must meet requirements for optimal assay performance. A written protocol should exist for monitoring conditions known to affect assay performance and instrumentation, and compliance should be documented.

	PERFORMANCE INDICATOR	FINDINGS Yes	No	In Progress	REFERENCES
Working Environment					
a.	Where appropriate, there are written criteria for acceptable environmental conditions.	☐	☐	☐	77,82
b.	Environmental conditions present meet manufacturer's recommended criteria for appropriate instrument operation	☐	☐	☐	82
c.	There are written procedures for correcting identified environmental problems.	☐	☐	☐	11,83
d.	There is appropriate and timely documentation of critical environmental variables.	☐	☐	☐	82
e.	Corrective actions are documented.	☐	☐	☐	84
f.	Space considerations meet appropriate standards for the working environment	☐	☐	☐	85,86,87
g.	Hallways and access areas are unobstructed	☐	☐	☐	87,88
h.	A procedure is in place that alerts appropriate personnel of service/maintenance activities that might impact laboratory testing processes (e.g. janitorial services, exterminators, painters, air conditioning maintenance, etc.).	☐	☐	☐	89

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IV. POST-ANALYTICAL CONSIDERATIONS

A. SCREENING TEST RESULTS - Screening results must be accurate and reported in a timely way. A procedure must exist for immediate reporting of results considered to indicate the possibility of a clinical emergency, including documentation of reporting and report receipt. A procedure should exist for quickly reporting unsuitable specimens so that repeat testing can occur in a timely way.

PERFORMANCE INDICATOR	FINDINGS Yes	No	In Progress	REFERENCES
1. Laboratory Assay Documentation:				
a. Post-analytic quality control activities are included in the laboratory procedure's manual.	☐	☐	☐	1,2,3,4,5
b. There is appropriate documentation of daily quality control results for each laboratory screening test.	☐	☐	☐	6
c. There is appropriate (comparative) documentation of long-term quality control (i.e. across lots of reagents, etc.)	☐	☐	☐	6,7
d. There is documentation of corrective action following a control failure.	☐	☐	☐	8,9
e. There is documentation of assessing trends in patient results(median, means, etc.).	☐	☐	☐	8,10
f. Assay quality control is reviewed and approved by a minimum of two qualified staff before results are released.	☐	☐	☐	10
g. There is a documented audit trail (date, and personnel identification when recording:				
i. Test results.	☐	☐	☐	11,12
ii. Quality control validation.	☐	☐	☐	11
iii. Assay completion and release.	☐	☐	☐	13
iv. Edits (if made).	☐	☐	☐	11
h. There are periodic audits (at least quarterly) by the quality assurance officer of all quality assurance documentation to assess overall analytical quality and verify that corrective actions have been successful.	☐	☐	☐	11
2. Laboratory Result Reporting:				
a. The system quality assurance plan addresses reporting of test results.	☐	☐	☐	4,9
b. There is a written policy that defines the timely reporting for all testing that includes "in-range", "out-of-range", and invalid results (preferably all results have been reported within 7 days of specimen receipt; "invalid" specimens have been reported within 24 hours of receipt; "out-of-range" results have been reported as quickly as possible).	☐	☐	☐	14
c. There is a process to audit whether a timely report has been generated for each specimen received (including "in-range", "out-of-range", and "invalid" reports).	☐	☐	☐	5,10,15,17
d. There is a separate reporting procedure defined for cases of immediate follow-up (including reporting protocol, information to be transmitted and documentation required).	☐	☐	☐	16
e. There is a daily audit of analytical activity that evaluates testing status for all specimens to ensure that:				
i. All specimens received (including previous days) are accounted for.	☐	☐	☐	18
ii. Any outstanding tests are scheduled for timely completion.	☐	☐	☐	10

f.	An efficient and effective system exists for transferring test results from the screening laboratory to the person(s) responsible for follow-up/tracking.	☐	☐	☐	19,20
g.	Where a computer system is used for reporting from the laboratory to the follow-up coordinator, a back-up system exists (fax, telephone, etc.) as an emergency contingency in case of a computer problem and its use is defined in the operations manual for both laboratory and follow-up staff.	☐	☐	☐	
h.	There is a predetermined time frame within which results requiring emergency follow-up are transmitted to the appropriate follow-up coordinator.	☐	☐	☐	16,19,20
i.	For telephone reporting of test results requiring immediate follow-up, there is documentation that includes name of person contacted, date, time, and by whom.	☐	☐	☐	16,21,22
j.	For telefax or other messaging of test results requiring immediate follow-up, there is documentation that results were sent including name of person sending.	☐	☐	☐	21
k.	For telefax or other messaging of test results requiring immediate follow-up, there is documentation that results were received including name of person receiving.	☐	☐	☐	21
l.	There is an appropriate means (staff and process) for communicating urgent testresults outside of usual working hours (weekends, holidays) when appropriate.	☐	☐	☐	23,24
m.	The result transfer process is periodically audited to ensure that it is timely and appropriately documented.	☐	☐	☐	19,20
n.	Laboratory reports are legible with information recorded in appropriate places.	☐	☐	☐	25
o.	Sufficient patient information is included in the transmitted laboratory report to appropriately and accurately identify the patient.	☐	☐	☐	26
p.	The format of the laboratory report is user-friendly.	☐	☐	☐	27
q.	The final laboratory report includes date of receipt and date of reporting.	☐	☐	☐	28,29
r.	Appropriate units of measure are noted if test values are reported.	☐	☐	☐	29,30,31
s.	Numerical values are not reported when outside of the established analytical range.	☐	☐	☐	30
t.	Expected results are given for each analyte or procedure reported.	☐	☐	☐	29,30
u.	There is a defined procedure for correcting reporting errors.	☐	☐	☐	32,33
v.	Corrections to reports are visibly noticeable	☐	☐	☐	32,34
w.	An audit trail documents who, what, why and when report edits were made.	☐	☐	☐	12,35

3. Records Storage (Including Reports, Results, and Residual Specimens):

a.	There is a defined and comprehensive procedure for retaining appropriate (defined by screening facility licensure requirements, local regulations and legal opinion) records.	☐	☐	☐	36,37,38,39
b.	There are defined data privacy safeguards for patient records in:				
	i. The screening laboratory.	☐	☐	☐	40
	ii. The case management area.	☐	☐	☐	40
c.	There is a written procedure defining appropriate specimen storage conditions for residual dried blood spots remaining after the completion of the screening tests.	☐	☐	☐	41,42
d.	There is a written policy regarding access to and use of residual dried blood spots.	☐	☐	☐	43,44,45,46
e.	There are appropriate policies regarding patient privacy relative to the storage and use of residual dried blood	☐	☐	☐	41,44,48

spots.

f.	There is a written procedure is for the eventual safe, secure disposal of residual dried blood spots.	☐	☐	☐	41,43
g.	Where use of dried blood spots for research is allowed, an Institutional Review Board ultimately approves the research use(s).	☐	☐	☐	47,49,50

C. SHORT-TERM FOLLOW-UP - Short-term follow-up begins with a screening result that requires follow-up and ends with resolution of the screening results (i.e. newborn diagnosed and accessing appropriate intervention activities, newborn not affected, or newborn lost to follow-up). Screening results requiring follow-up (as defined by CLSI/NCCLS Follow-up Guidelines) include: (1) "invalid" - screening process could not be completed according to established criteria (unsuitable specimen or test, no specimen, or incomplete information), and (2) "out-of-range" - any screening result outside of the expected range of testing results established for a particular condition (includes carrier results and any findings indicating the need for further testing).

PERFORMANCE INDICATOR	FINDINGS Yes	No	In Progress	REFERENCES
1. Follow-up Procedures:				
a. A defined protocol exists for actively following/tracking specimens with screening results that are:				
i. "Out-of range."	☐	☐	☐	59,60,62
ii. "Invalid."	☐	☐	☐	59,60,62
b. All follow-up/tracking protocols for "out-of-range" or "invalid" screening test results are "closed loops" that have clearly defined:				
i. Starting actions (e.g. telephone call or letter).	☐	☐	☐	53,62
ii. Monitoring actions (specimen monitoring, follow-up calls/letters, nurse visits etc.)	☐	☐	☐	53,62
iii. End points (when follow-up activities have exhausted all reasonable avenues of contact).	☐	☐	☐	53,62
c. The follow-up protocols for each type of testing result (above) includes specifics for immediate notification of:				
i. Specimen submitter.	☐	☐	☐	61,62
ii. Primary care practitioner.	☐	☐	☐	61,62
iii. Parents/guardians.	☐	☐	☐	61,62
d. All documentation requirements for follow-up steps are clearly defined.	☐	☐	☐	53,55
e. For "out-of-range" results, the notification process includes an urgent request for appropriate follow-up action. which may include requesting a repeat newborn screen, serum confirmatory testing, clinical evaluation, etc.	☐	☐	☐	59,60,62
f. Specimens requested as a result of an "out-of-range" initial result (requiring a repeat heelstick specimen instead of serum confirmation) are closely monitored to ensure timely specimen receipt.	☐	☐	☐	59,60,62
g. Other actions requested as a result of an "out-of-range" initial result, including serum testing, and clinical evaluation are monitored according to a time-line consistent with rapid resolution of all screening test results.	☐	☐	☐	59,60,62
h. For "invalid" specimens, notifications include an urgent request for obtaining an immediate repeat specimen.	☐	☐	☐	59,60,62
i. The "invalid" notifications include an explanation of the reason for the repeat request, including why a specimen may have been considered "invalid."	☐	☐	☐	62,63,64
j. Specimens requested as a result of an "invalid" initial submission are monitored to ensure timely specimen receipt.	☐	☐	☐	60,62
k. Procedures for follow-up actions and activities exist in printed form (manual - may also be electronic) that include:				

i.	A permanent historical record of all procedural changes over time (i.e. permanent reference manual).	☐	☐	☐	51,52,53
ii.	Documentation (date and signature) of annual review by the follow-up supervisor.	☐	☐	☐	51,52,53
iii.	Documentation (date and initials) of procedural changes at the time changes were implemented.	☐	☐	☐	51,52,53
iv.	Detailed follow-up/tracking protocols for each screened condition (flow charts optional).	☐	☐	☐	53
v.	A working copy readily available for employee use containing proper documentation of review and update.	☐	☐	☐	51,52,53
l.	The follow-up procedures manual is checked at least annually to ensure that the appropriate documented reviews/ changes have occurred and that signatures, dates, and initials are in place.	☐	☐	☐	54
m.	The follow-up process includes a mechanism for direct communication with parents if other communications procedures fail.	☐	☐	☐	54,62
n.	The follow-up procedures include accumulating and recording summation data ("out-of-range" results tracked, number confirmed, number lost, time to diagnosis, etc.)	☐	☐	☐	56,62
o.	Appropriate follow-up data are reported to the national newborn screening database as quickly as possible.	☐	☐	☐	57,58
p.	The national database is periodically reviewed to ensure that program data are accurate and complete.	☐	☐	☐	57,58

2. <u>Follow-up Communication:</u>

a.	Written scripts are available for guidance where telephone contact is prescribed.	☐	☐	☐	65,66
b.	Letters used as part of follow-up are reviewed by appropriate advisors, consultants and parent recipients, and are found to be:				
i.	Consistent.	☐	☐	☐	66
ii.	Accurate.	☐	☐	☐	67
iii.	Brief, concise and easy to understand.	☐	☐	☐	67
iv.	Informative.	☐	☐	☐	66
v.	Sensitive (firm but avoiding unnecessary alarm) .	☐	☐	☐	67,68,69,70
vi.	Of appropriate literacy level.	☐	☐	☐	71-76
c.	Concise, informative, next action steps are available for the health care professional (ACT Sheets).	☐	☐	☐	66,77
d.	Appropriate, basic educational materials accompany any letters sent to parents regarding testing results.	☐	☐	☐	66
e.	Adequate number of trained and qualified follow-up staff are available to accomplish required communications tasks with access to other sources of information should additional information be needed.	☐	☐	☐	78,79
f.	Protocols detail work coverage and communications that might be necessary outside of normal working hours (including weekends and holidays) as a result of available laboratory test results.	☐	☐	☐	80
g.	Documentation of communication processes conforms to the follow-up operations manual.	☐	☐	☐	81
h.	Documentation of communications concerning test results includes:				
i.	Date.	☐	☐	☐	81
ii.	Time.	☐	☐	☐	81
iii.	Type of communication.	☐	☐	☐	81
iv.	Name of person communicating the information.	☐	☐	☐	81
v.	Name of person receiving the information.	☐	☐	☐	81

vi.	Explanatory notes.	☐	☐	☐	81
i.	Documentation of follow-up endpoint/case dispostion includes:				
i.	Final case disposition (affected, not affected, lost to follow-up.	☐	☐	☐	81
ii.	Date evaluated to confirm screening results.	☐	☐	☐	81
iii.	Date of diagnosis/case disposition.	☐	☐	☐	81
iv.	Treatment/intervention date (if applicable).	☐	☐	☐	81
v.	Test results on which diagnosis was based.	☐	☐	☐	82
vi.	Name of person communicating diagnosis information.	☐	☐	☐	81
vii.	For diagnosed cases (i.e. affected), referral information (e.g. sub-specialty provider, support services) and enrollment in early intervention, and long-term follow-up activities	☐	☐	☐	81
viii.	For cases with uncertain diagnosis, clinical surveillance and action plan to achieve case resolution.	☐	☐	☐	81
ix.	Other information deemed useful (i.e. predetermined by the program).	☐	☐	☐	81
x.	Identification of the person recording/entering the information.	☐	☐	☐	81

C. FOLLOW-UP SUPPORT ACTIVITIES – So that there is uniformity to diagnostic and educational approaches subsequent to screening, there are certain support activities that must be considered and addressed by the newborn screening system. These include the way in which the screening test results are interpreted by healthcare practitioners and the resulting approaches to diagnosis and treatment, and the way in which educational/counseling information for parents of newborns identified for further testing and/or diagnosed with one of the screened conditions is presented.

	PERFORMANCE INDICATOR	FINDINGS Yes	No	In Progress	REFERENCES
1.	**Diagnosis:**				
a.	A general diagnostic protocol developed by subspecialty consultants exists for each condition screened.	☐	☐	☐	62,82
b.	Access to diagnostic services is facilitated and monitored as part of the follow-up activities.	☐	☐	☐	62,83,79
c.	Suggested diagnostic protocols developed in cooperation with appropriate subspecialty consultation/input or following national guidelines are available to primary healthcare providers (may be in Provider Manual).	☐	☐	☐	62,82,89
d.	The suggested diagnostic protocols are periodically reviewed and updated by appropriate subspecialists.	☐	☐	☐	62,82,85
e.	Case definitions for each screened condition (including appropriate clinical and/or biochemical indicators) exist for each screened condition so that diagnoses are unambiguous.	☐	☐	☐	62,2,85
f.	Defining biochemical/clinical data are documented at the time of diagnosis to ensure adherence to definitions for conditions reported.	☐	☐	☐	62,82,85
g.	Appropriate diagnostic data are reported to the national newborn screening information system in a timely way.	☐	☐	☐	62
2.	**Parent Education:**				
a.	Educational materials discussing screening results are available in compliance with the educational plan of the newborn screening program,	☐	☐	☐	85,86

b.	Health professionals, often representing the newborn's medical home, are provided with appropriate information to facilitate initial contact with parents about "invalid" or "out-of-range" test results with encouragement to present the information in an informative and sensitive way.	☐	☐	☐	85
c.	Access to a multi-disciplinary team is available to provide and accurate information and support to the family [including face-to-face contact(s) if desired or needed].	☐	☐	☐	85
d.	Condition-specific action information (ACT Sheets) are available and transmitted to healthcare practitioners along with "out-of-range" results. (ACT sheets contain essential stepwise actions supplied "just in time" for physician use.)	☐	☐	☐	77
e.	Condition-specific educational information that is accurate, culturally sensitive and of appropriate literacy level is available for the parent(s) when a suspected condition is diagnosed.	☐	☐	☐	86
f.	The parent educational materials provided in support of presumptive or confirmed diagnosis:				
	i. Adhere to the written educational plan.	☐	☐	☐	90,91
	ii. Are accurate (as determined by an appropriate subspecialty consultant).	☐	☐	☐	88
	iii. Are current (as determined by an appropriate subspecialty consultant).	☐	☐	☐	88
	iv. Are simple (as determined by parent users).	☐	☐	☐	88
	v. Are available free of charge in a variety of formats (e.g. brochure, video, lay publications, website, etc.).	☐	☐	☐	91
	vi. Meet appropriate literacy standards (5th grade or lower).	☐	☐	☐	69,70,71,72
	vii. Are attractive and eye catching (as determined by parent users).	☐	☐	☐	84
	viii. Meet their intended use (are evaluated for impact by parent users).	☐	☐	☐	85
	ix. Are available in appropriate languages.	☐	☐	☐	83
	x. Are distributed in a timely manner.	☐	☐	☐	69,70,71,72
g.	Diagnostic, condition-specific educational information is available for primary care practitioners as needed (i.e. Fact Sheets – more comprehensive than ACT sheets listed above).	☐	☐	☐	82
h.	Information is available concerning available parent support networks/groups.	☐	☐	☐	86
i.	Contact information is available to obtain supplemental information or further explanations of distributed materials if needed.	☐	☐	☐	82
j.	A procedure is in place for systematically reviewing and updating the diagnostic educational materials (including parent input).	☐	☐	☐	82
k.	Distribution records of all educational materials are maintained.	☐	☐	☐	59
l.	Periodic assessment of availability of educational materials occurs through random checks of distribution sites.	☐	☐	☐	
m.	All condition-specific educational material (professional and parent) is reviewed annually to ensure accuracy.	☐	☐	☐	

3. <u>Counseling (Including Nutritional, Genetics, etc.):</u>

a.	Qualifications of counselors (where used) have been defined by the newborn screening program with input from stakeholders and the program's advisory committee.	☐	☐	☐	92,93,94
b.	Where counseling is appropriate and provided, the general expectations have been defined for consistency and quality.	☐	☐	☐	92,93,94
c.	Where counseling is appropriate and provided, healthcare providers and parents are advised of its availability.	☐	☐	☐	92,93,94

d.	Counseling services provided are documented in the patient's newborn screening follow-up record.	☐	☐	☐	92,93,94
e.	Parents are periodically asked to evaluate the counseling provided and to identify other possible needs that could be met through the newborn screening program.	☐	☐	☐	92,93,94

4. Medical Management:

a.	Subspecialists and appropriate treatment centers are identified and a listing is available for use by primary healthcare providers.	☐	☐	☐	97,84
b.	A general (consensus) medical management protocol, developed by subspecialty consultants exists for each screened condition.	☐	☐	☐	95,96,97
c.	The suggested medical management protocols are current and available to primary healthcare providers for guidance as needed (may be in Provider Manual).	☐	☐	☐	95,96,97
d.	The medical management protocols are periodically reviewed and updated by appropriate subspecialists.	☐	☐	☐	95,96,97
e.	Parents are periodically asked to evaluate medical services provided and to identify other possible needs that could be met through the newborn screening program.	☐	☐	☐	95,96,97

D. PROGRAM EVALUATION – In order to determine whether and how the goals of newborn screening are being met, and to refine and improve the newborn screening system, it is appropriate to periodically and continuously evaluate selected indicators. An Evaluation Plan should exist that clearly defines the selected indicators, assigns responsibility for their monitoring, and outlines the periodicity with which evaluations are to occur. Program evaluation should encompass both short-term and long-term activities.

	PERFORMANCE INDICATOR	FINDINGS Yes	No	In Progress	REFERENCES
1.	**Short-Term Program Evaluation**				
a.	The follow-up operations manual includes a plan for evaluating the short-term follow-up process.	☐	☐	☐	98-102
b.	Short-term follow-up performance indicators have been defined in cooperation with other stakeholders within the screening system (i.e. advisory committee, etc.)	☐	☐	☐	97
c.	Short-term program performance indicators include data elements requested in the national reporting scheme (i.e. National Newborn Screening Information System).	☐	☐	☐	57,58
d.	The program evaluation data collected are assessed on a prescribed periodic basis.	☐	☐	☐	100
e.	System changes are considered on the basis of the periodic data evaluations, and resulting changes are appropriately documented.	☐	☐	☐	100,102,103
f.	As a part of the evaluation process for screening and short-term follow-up, there is:				
	i. A defined process for obtaining clinical feedback for each condition diagnosed.	☐	☐	☐	3,18,99,97,101
	ii. A defined procedure for investigating and reconciling unexplained differences between screening results and clinical findings.	☐	☐	☐	3,18,99,97
	iii. Documentation of the process steps for resolving significant differences between screening laboratory test	☐	☐	☐	3,18,51,101,

	results and confirmatory laboratory test results.				
iv.	A periodic review of recall rates for each screened condition (within the program and in comparison to other programs) with the goal of decreasing recall without missing cases.	☐	☐	☐	3,18,51,101
v.	A periodic review of laboratory result trends (i.e. excessive "out-of-range" results, etc.) to aid in detecting analytical or other aberrations (e.g. kit problems, transport problems, etc.)	☐	☐	☐	3,18,51,101,
vi.	A plan for corrective action when adverse result reporting trends are identified (e.g. reassess kit calibrators, review collection/transmittal procedures).	☐	☐	☐	3,9, 18,110,111,
vii.	A protocol for reevaluating/confirming initial "in-range" test results when an "out-of-range" result on a subsequent specimen leads to a diagnosis.	☐	☐	☐	3,18,101
viii.	Ongoing review of initial test data when an "out-of-range" result on a subsequent specimen results in a a confirmed diagnosis (including repeating the initial and subsequent tests in the same assay).	☐	☐	☐	3,18,101
ix.	A protocol for resolving complaints received as a result of the follow-up process.	☐	☐	☐	51
x.	A process for providing feedback to the screening laboratory when suspected conditions are confirmed.	☐	☐	☐	3,18,51,101
g.	The condition-specific data periodically evaluated include:				
i.	The number of cases requiring follow-up for "out-of-range" results.	☐	☐	☐	101,102,103
ii.	The number of confirmed cases (with appropriate biochemical/clinical back-up information).	☐	☐	☐	101,102,103
iii.	The number of cases for which "out-of-range" test result follow-up could not be completed (with back-up information).	☐	☐	☐	101,102,103
iv.	The number of cases requiring follow-up for an "invalid" specimen.	☐	☐	☐	101,102,103
v.	The time from birth to diagnosis and intervening steps (receipt at laboratory, result available, physician contacted).	☐	☐	☐	101,102,103
vi.	Whether the case was diagnosed as a result of a second screen following an initial "in-range" (normal) screening result.	☐	☐	☐	101,102,103
h.	An annual report of program evaluation data is published and disseminated in order to provide information for interested stakeholders and the public.	☐	☐	☐	104,102,103
i.	The services of diagnostic laboratories are periodically evaluated and efforts made to resolve any problems identified.	☐	☐	☐	105,106
j.	The efficacy of the short-term follow-up system is periodically evaluated based on program data and refined as needed to improve overall follow-up activities.	☐	☐	☐	105,106
2.	**Long-Term Program Evaluation (Including Medical Management):**				
a.	A plan exists for periodically assessing patient progress thorough review of the defined outcome indicators.	☐	☐	☐	95,101,107,56
b.	Long-term outcome indicators have been developed in consultation with appropriate subspecialty expertise for each screened condition.	☐	☐	☐	85
c.	Long-term outcome indicators are periodically reviewed for suitability by appropriate subspecialty consultants and updated as needed.	☐	☐	☐	60,54
d.	Long-term outcome data are periodically solicited, compiled and evaluated, from families primary care providers and/or subspecialists.	☐	☐	☐	85

e.	Long-term outcome data are compared with expected state and national goals, and the information shared in the program's annual report.	☐	☐	☐	108,104
f.	Program improvements are initiated on the basis of long-term program evaluation data.	☐	☐	☐	90
g.	Appropriate medical management indicators, developed by subspecialty consultants, exist for each condition.	☐	☐	☐	60
h.	Medical management indicators are periodically reviewed for suitability by subspecialty consultants and the advisory committee, and updated as appropriate.	☐	☐	☐	60,96
i.	Medical management outcome data are periodically collected, evaluated and reported to the newborn screening program's advisory committee.	☐	☐	☐	60,96,109

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Person(s) conducting evaluation *(Note: Because of the complexities of the various sections of the newborn screening to be evaluated, It is suggested that at least two persons complete the overall assessment including one person with laboratory expertise and one with program management/follow-up/education expertise)*.

Laboratory Assessment:

Program (If other than State Public Health Laboratory)

Printed Name

Position

Signature

Date

Program Management/Follow-up/Education Assessment:

Printed Name

Position

Signature

Date