

Attachment G--Newborn Screening LABORATORY data collection

Form Approved
OMB No. 0920-0879
Expiration Date: 03/31/2014

The Centers for Disease Control and Prevention's Newborn Screening and Molecular Biology Branch (CDC NSMBB) is seeking your input to assess the needs of state newborn screening laboratories and inform current and future CDC NSMBB activities. CDC NSMBB houses the Newborn Screening Quality Assurance Program (NSQAP) and the recently created Molecular Assessment Program (MAP).

*** 1. Which state(s) and/or region(s) does your newborn screening laboratory serve? In the box below, please type all regions covered by your newborn screening laboratory.**

*** 2. Please tell us how much you agree or disagree with each statement about CDC NSMBB activities.**

	Strongly Agree	Agree	Neutral	Disagree	Strongly Disagree	Don't Know/Not Applicable
a. CDC NSMBB is a trusted resource for state newborn screening laboratories.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
b. CDC NSMBB's Newborn Screening Quality Assurance Program materials help state newborn screening laboratories address CLIA and other regulatory requirements.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
c. Access to CDC NSMBB's technical expertise promotes quality within state newborn screening laboratories.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
d. Access to CDC NSMBB's educational and training opportunities promote quality within state newborn screening laboratories.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
e. Access to CDC NSMBB's Molecular Assessment Program promotes quality within state newborn screening laboratories.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

Please provide any additional information that should be considered when assessing CDC NSMBB's impact on state newborn screening laboratories.

Public reporting burden of this collection of information is estimated to average 20 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. An agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to CDC/ATSDR Information Collection Review Office, 1600 Clifton Road NE, MS D-74, Atlanta, Georgia 30333; ATTN: PRA (0920-0879).

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*3. Please tell us how much you agree or disagree with each statement about potential CDC NSMBB efforts.

	Strongly Agree	Agree	Neutral	Disagree	Strongly Disagree	Don't Know/Not Applicable
a. CDC NSMBB should support pilot studies to harmonize newborn screening results across testing platforms.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
b. CDC NSMBB should support pilot studies to promote implementation of new newborn screening tests within state newborn screening laboratories.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
c. CDC NSMBB should enhance web-based educational opportunities, such as technology-driven and issue-based webinars, for state newborn screening laboratories	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

Please provide any additional information about activities CDC NSMBB should consider to better support state newborn screening laboratories.

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Measurement of succinylacetone (SUAC) in newborn screening laboratories.

The following questions relate to measurement of SUAC in your newborn screening laboratory.

***4. Does your laboratory measure succinylacetone (SUAC) in dried blood spots?**

- Yes
- No

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Measurement of succinylacetone (SUAC) in newborn screening laboratories.

***5. Here are some items related to SUAC for labs currently measuring it.**

	Yes	No	N/A
a. Do you report isolated elevations of tyrosine levels?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
b. Do you have cut offs for tyrosine based on birth weight?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
c. Do you have cut offs for tyrosine based on gestational age?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
d. Do you report elevated SUAC levels?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
e. Do you perform SUAC analysis only in response to an elevated tyrosine? (i.e. SUAC analysis is only performed as a second-tier test)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
f. Do you use SUAC and tyrosine as markers to identify infants with Tyrosinemia Type 1?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
g. Were budgetary restrictions an obstacle to SUAC implementation in your laboratory?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
h. Were technical resources and personnel issues considered obstacles to SUAC implementation in your laboratory? (e.g. were additional staff or instruments required for testing)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

i. What were the major challenges to implementing SUAC testing in your laboratory? How were they overcome?

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Measurement of succinylacetone (SUAC) in newborn screening laboratories.

*6. Here are some items related to SUAC for labs not currently measuring it.

	Yes	No	N/A
a. Do you report isolated elevations of tyrosine levels only?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
b. Do you have cut offs for tyrosine based on gestational age?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
c. Do you have cut offs for tyrosine based on birth weight?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
d. Is your laboratory considering the adoption of SUAC testing?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
e. Does your laboratory have, or is it requesting, the necessary funding, infrastructure, staff, and technical expertise to pilot SUAC testing?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
f. Are budgetary restrictions an obstacle to SUAC implementation in your laboratory?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
g. Are insufficient technical resources and personnel an obstacle to SUAC implementation in your laboratory? (e.g. were additional staff or instruments are required for testing)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
h. Is the current use of an assay that does not measure SUAC an obstacle to implementing SUAC testing in your laboratory?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
i. Would a formal recommendation to use SUAC as the primary marker for Tyrosinemia Type 1, issued by the Secretary's Advisory Committee on Heritable Disorders on Newborns and Children (SACHDNC), increase the likelihood of SUAC testing by your laboratory?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
j. Would a formal recommendation to use SUAC as the primary marker for Tyrosinemia Type 1, issued by the Secretary of the Department of Health and Human Services, increase the likelihood of SUAC testing by your laboratory?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
k. What do you consider to be your laboratory's largest challenges to implementing SUAC testing? (e.g. why would it be difficult to integrate SUAC testing into the current workflow of your NBS laboratory?)			

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Thank you for your responses. Press DONE to submit the survey.