

**CDC Newborn Screening Quality Assurance Program – Pilot Online Data Collection for Spinal
Muscular Atrophy (SMA) Proficiency Testing (PT)**

CSTLTS Generic Data collection Request
OMB No. 0920-0879

Supporting Statement – Section B

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Section B – Data collection Procedures

1. Respondent Universe and Sampling Methods

It is expected that there will be 40 participants. These participants are clinical laboratory technologists/technicians from public health labs that perform newborn screening and/or develop newborn screening tests. In total, there are more than 450 enrolled labs that use SMA PT as a service. Those 40 who have contacted CDC in the past 15 months inquiring about SMA PT service will be invited to participate in this pilot.

2. Procedures for the Collection of Information

Respondents will be recruited through an invitation email (see **Attachment D – Pilot Online Data Collection for SMA PT Email Invitation**) to the respondent universe. Respondents will have 2 weeks to indicate their willingness to participate. Two business days before shipment, respondents who request to participate will receive a notification email that will explain:

- The purpose of the data collection, and why their participation is important
- Instructions for participating
- Method to safeguard their responses
- That participation is voluntary
- The expected time to complete the instruments
- Contact information for the project team

1) Data will be collected via an online reporting site (see **Attachment A – Pilot Online Data Collection for SMA PT Screenshot of Reporting Page** and **Attachment B – Pilot Online Data Collection for SMA PT Feedback Form**) sent as an attachment to an email notification (see **Attachment E – Pilot Online Data Collection for SMA PT Email Packet**) 2 days before shipment of PT panels. Participants will have 4 weeks to complete and return the data. A reminder email (see **Attachment F – Pilot Online Data Collection for SMA PT Email Reminder**) will be sent to participants who have not submitted data 1 week before the participation deadline.

Data analysis will involve simple as well as categorical statistics. Individual respondents will receive an evaluation of their performance (actual versus expected outcome per PT specimen). This evaluation will not be shared with any other participant. All participants will receive an event summary report containing aggregate statistical data (aggregate PT outcomes). The use of custom Lab IDs known only to CDC and respondent maintains confidentiality of the data. A summary report of the aggregate interval scale feedback will be provided to CDC program staff in order to inform program improvements.

3. Methods to Maximize Response Rates Deal with Nonresponse

Although participation in the data collection is voluntary, the project team will make every effort to maximize the rate of response. Labs that had previously requested and/or shown interest in this service are included as participants in the pilot, which is expected to increase response rates. The data collection instruments were designed to limit questions to collect only required information with the minimum number of free-response questions, thereby minimizing response burden.

Two business days before shipping the PT panels, an email notification will be distributed (see **Attachment E – Pilot Online Data Collection for SMA PT Email Packet**) containing the customer service feedback form (see **Attachment B – Pilot Online Data Collection for SMA PT Feedback Form**) and instruction sheet (see **Attachment G – Pilot Online Data Collection for SMA PT Instructions**). Respondents will have 15 business days to complete the instrument. Those who do not respond within 10 business days will receive a reminder email (see **Attachment F – Pilot Online Data Collection for SMA PT Email Reminder**) urging them to complete the instruments. Those who do not respond within 5 business days from the reminder email will be considered non-responders.

4. Test of Procedures or Methods to be Undertaken

Pilot SMA PT Data Reporting Page

The estimate for burden hours is based on testing of the Data Reporting Page (**Attachment A**) by 1 public health professional and 1 IT professional. In the pilot test, the average time to complete the instrument including time for reviewing instructions, gathering needed information and completing the instrument, was approximately 5 minutes (range: 4 – 6). For the purposes of estimating burden hours, the upper limit of this range (i.e., 6 minutes) is used.

Pilot of Online Data Collection for SMA PT Feedback Form

The estimate for burden hours is based on a pilot test of the Feedback Form (**Attachment B**) by 2 public health professionals. In the pilot test, the average time to complete the instrument including time for reviewing instructions, gathering needed information and completing the instrument, was approximately 2.5 minutes (range: 2 –3). For the purposes of estimating burden hours, the upper limit of this range (i.e., 3 minutes) is used.

5. Individuals Consulted on Statistical Aspects and Individuals Collecting and/or Analyzing Data

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LIST OF ATTACHMENTS – Section B

Note: Attachments are included as separate files as instructed.

- 1) **Attachment A – Pilot Online Data Collection for SMA PT Screenshot of Reporting Page**
- 2) **Attachment B – Pilot Online Data Collection for SMA PT Feedback Form**
- 3) **Attachment D – Pilot Online Data Collection for SMA PT Email Invitation**
- 4) **Attachment E - Pilot Online Data Collection for SMA PT Email Packet**
- 5) **Attachment F – Pilot Online Data Collection for SMA PT Email Reminder**
- 6) **Attachment G – Pilot Online Data Collection for SMA PT Instructions**