Proof of Concept Project
Newborn Screening
Pre-Analytical Process Improvement

Electronic Data Exchange with a Montana Hospital: Final Report

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Milestones and Report Prepared by:

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Contents
Introduction ........................................................................................................................................... 3
Methods .................................................................................................................................................. 4
   Table 1. Preanalytical Metrics Used for Project Evaluation .............................................................. 5
Results ................................................................................................................................................... 5
   Figure 1. Order Entry Workflow Process at CMC .............................................................................. 9
Project Evaluation .............................................................................................................................. 10
   Table 2. Baseline Data for Evaluation Metrics .................................................................................. 10
Lessons Learned .................................................................................................................................... 10
Barriers, Concerns, and Other Issues to be Resolved ........................................................................ 11
Next Steps and Sustainability ............................................................................................................. 12
Gaps in the Overall Project ................................................................................................................ 13
Conclusion: ........................................................................................................................................... 13
Appendix 1: Examples of Birth Notification Data ............................................................................... 14
   Figure 1: Baby demographic data in Copia, test message sent from CMC ...................................... 14
   Figure 2: HL7 Message of ADT data in Copia .................................................................................. 15
   Figure 3: Ask at Order Entry (AOE) Questions at CMC ................................................................. 16
   Figure 4: HL7 Order Update Message with AOE Questions in Copia ............................................ 17
   Figure 5: Data Contents of HL7 test message sent from CMC to MTPHL ....................................... 18
Appendix 2: Example of NBS Quality Report Card ........................................................................... 19
Appendix 3: Process Mapping Worksheets ....................................................................................... 21
   Preanalytical Specimen Collection and Transport (CMC) .............................................................. 21
   Specimen Review and Accessioning (MTPHL) ................................................................................ 22
   Data Entry including Verification of Data ........................................................................................ 23
**Introduction**

This proof-of-concept project tested the feasibility of establishing electronic data exchange for birth notifications, Newborn Screening (NBS) test orders and NBS test results between the Montana Public Health Laboratory (MTPHL) and Missoula Community Medical Center (CMC). The initial goals of this project were to:

1) Establish birth notification electronic connectivity in addition to electronic HL7 order entry and results reporting (OE/RR) between MTPHL and CMC for NBS samples and tests by December 2014

2) Monitor pre-analytic and post-analytic metrics over the course of the project to see if designed interventions utilizing the electronic birth notification and electronic OE/RR would improve the accuracy of information and the timeliness and quality of NBS specimens

3) Determine the impact of targeted communications about specimen collection, submission and handling issues, and more timely follow-up practices as a result of electronic messaging

The MTPHL currently does not have an electronic HL7 connection for receiving test orders and reporting results with any hospital laboratory submitting NBS specimens. The MTPHL has a unique hybrid model for providing newborn screening services. Certain screening tests are performed at the MTPHL, and the remaining screens, including testing by MS/MS, are referred to the Wisconsin State Laboratory of Hygiene. The birth rate in Montana is approx. 12,000/year, and only a single screen is required, as long as the specimen is collected properly and within the prescribed time frame. The majority of NBS specimens are transported to the MTPHL by a contracted courier, Monday - Friday, and specimens are processed and tested Monday – Friday and only processed for submission to Wisconsin on Saturday. MTPHL recently began providing quarterly feedback on pre- and post-analytical processes to birthing facilities by using a NBS report card. The NBS report card provides data on the percentage of unsatisfactory specimens, the timeliness of specimen collection, and the timeliness of specimen submission.

One benefit of electronic connectivity is expected to be improvement of preanalytical quality metrics. MTPHL began coordinating with one hospital laboratory, Missoula Community Medical Center (CMC) in August 2014 to set up a bidirectional HL7 compliant electronic order entry/results reporting (OE/RR) interface between CMC’s Cerner LIMS and the Copia/Harvest LIMS (Orchard Software Corp) at MTPHL. CMC accounts for approximately 15% of the total NBS specimens submitted. This project required the addition of an electronic message containing demographic information at the time of birth, prior to specimen collection, which is captured in the MTPHL LIMS patient record. Baseline data for pre-analytic process metrics were defined and gathered, and this data was expected to be used in comparison to post-electronic connection data.
Methods

The MTPHL Director (Ron Paul) and Laboratory Systems Improvement Laboratory Manager (Susie Zanto) provided support, guidance, data management, and quality improvement and project evaluation experience for this project. MTPHL contracted with a project manager, Anne Weber (LabLogic), former MTPHL Director, to provide support specific to this project by coordinating communication with project partners, tracking project progress, monitoring data, and drafting milestone and final reports.

Communication with project partners was the most critical component of the project. Weekly check-in conference calls with project partners were conducted, moderated by Susie Zanto with backup by Anne Weber, to discuss the current status and next steps for achieving electronic connectivity. Call notes were distributed weekly to all participants, prior to the next call. The project partners are listed below:

- Alwin Church MT(ASCP), Sr. Clinical IT Applications Analyst – Laboratory, CMC
- Ron Adams MCITP DBA - Interface Analyst, CMC
- Ryan Dunn, Network Engineer, CMC
- Steve Boone, NCIE, NCDA, VCP, Network Engineer - IT Operations, CMC
- Tim Determan, Information Systems Bureau, Montana Department of Public Health and Human Services (DPHHS)
- Jesus Garcia, HL7 Interface Specialist, Orchard Software Corporation
- Kay Hoff, Clinical IT Applications Specialist—Laboratory, CMC; added in late May, 2015, following Alwin Church leaving employment with CMC.

Calls were held beginning on December 17, 2014 and will continue through the end of June. The initial goal for this project was to establish the electronic transmission of birth notification from CMC using their Cerner information system to the MTPHL LIMS (Copia), and this goal was accomplished. Once this birth notification data was received, the next steps are to use this data for pre-analytical improvements in accuracy and timeliness. This process is ongoing.

The effectiveness and impact of this project were expected to be measured and evaluated by utilizing existing data stored in the Harvest/Copia LIMS system and in the iPassport quality management system software, using quality improvement tools and expertise already in place at the MTPHL. The metrics chosen for evaluation of this project are listed in Table 1. Baseline data were calculated to use as a comparator for the effectiveness of this proof of concept project, when all of the data fields needed in the birth notification message are received into Copia, and we “go live” with the incoming messages. This is expected within 30 days of this report.
Table 1. Preanalytical Metrics Used for Project Evaluation

<table>
<thead>
<tr>
<th>Measurable Metric</th>
</tr>
</thead>
<tbody>
<tr>
<td>Average time from birth to NBS specimen collection</td>
</tr>
<tr>
<td>Average time from collection to receipt at the MTPHL</td>
</tr>
<tr>
<td>Percentage of unsatisfactory specimens</td>
</tr>
<tr>
<td>Number of NBS specimens with missing or inaccurate relevant data</td>
</tr>
<tr>
<td>Number of corrected or amended NBS reports</td>
</tr>
</tbody>
</table>

An assessment of the project was done at approximately 3 months and 6 months post-implementation to determine whether expected outcomes for pre- and post-analytical process improvement were being achieved, or at least trending to success, and if not, why. These assessments were reported as milestones on the APHL SharePoint website.

Project goals and accomplishments were presented in the session titled *Newborn Screening Pre-analytic Initiatives* on May 21, 2015 at the APHL Annual Meeting by Susanne Zanto.

While data transmission testing was ongoing in June 2015, preanalytical process mapping was conducted at MTPHL to discuss the additional birth data with laboratory staff members and determine the process changes and quality metrics that might occur with use of the data. Two process mapping meetings were facilitated by Anne Weber with an initial overview given by Susie Zanto, and participants included all the MTPHL staff in the NBS laboratory: Vicky Tiberi (Supervisor), Linda Beischel (NBS Follow-up Coordinator), Bob Sampsel, Walter Walsh, Tammy Buckley, Jody Coopersmith and Keith Baker (Clinical Laboratory Specialists). The process mapping discussions covered the current processes for collection and transport of the specimen to MTPHL and specimen accessioning into Harvest at MTPHL. Possible ways that birth notification data and electronic HL7 test orders could be used to improve preanalytical processes was also discussed.

Following the process mapping meetings, a final report was written and submitted.

**Results**

Through weekly communication among the project partners, the electronic connectivity process was discussed and mapped out. Although these steps were not outlined at the beginning, in the end, the process had the following steps and outcomes:

1. **Determine the method of message transmission.** Because of security limitations at DPHHS, file transfer is only allowed using secure file transfer protocol (sFTP), and SSL certificates. Electronic messages, both demographic (ADT) and orders (ORM), from CMC would be pushed to a MT sFTP
folder where they would be automatically transferred to a folder accessible by Copia. Results messages from MTPHL would be routed to a sFTP folder accessible by CMC. CMC will both push order messages and pull results messages and MTPHL would deliver and pick up messages, all at defined time intervals.

Outcome: Messages were successfully sent from CMC to MTPHL using the secure FTP folders.

2. **Determine the birth notification data fields needed from CMC.** MTPHL determined which data fields needed to be submitted at the time of birth notification, and which data fields could be submitted with the NBS testing order. A standard HL7 message is used so that information is populated in the correct demographic fields.

Outcome: The identified relevant data fields for the birth notification ADT message from CMC are:

   a. Hospital of Birth  
   b. Mother's Name  
   c. Mother's Contact Information  
   d. Baby's Home Address  
   e. Baby's Physician  
   f. Is the Baby in NICU or the "regular" Nursery  
   g. Date and Time of Birth  
   h. Gender of Baby  
   i. Single or Multiple Birth (A, B, C)

3. **Determine how birth notification data would be sent from CMC.** It is desirable to receive birth notification data in real time, so that interventions could be taken as soon as possible, if needed. Although the LIMS system at CMC has both test and production environments, Copia/Harvest does not, and test orders are received into the MTPHL Production LIMS. To denote these test patients, it was agreed to add two letters—zz—to the beginning of each patient’s last name. Adding these letters is a standard practice at MTPHL to indicate “test” patients in Harvest. So although real patients were used, the electronic messages were recognized as testing messages in the MTPHL system.

Outcome: CMC developed programming that automatically sends data from the live birth registration record to the MTPHL Copia production environment. The timing of this data transmission can be set by the programmers, and the transmission is currently sent every 15 minutes.

4. **Determine how birth notification data would populate the MTPHL LIMS.** Although it was originally expected that the birth notification data would be captured in Copia as an uncollected
pending order, further information from Orchard Software dictated a different approach. The birth notification message is used to populate demographic fields in Copia using standard HL7 messaging.

**Outcome:** Birth notification data can be received at MTPHL before specimens are collected. Copia stores the birth notification information in individual patient demographic records. Test messages containing birth notification data from CMC populated the correct data fields in Copia (see Figures 1 & 2 in Appendix 1).

5. **Determine how NICU information would be placed in the CMC birth notification message.** MTPHL was not receiving the NICU designation in the expected field; instead is getting NWB (new well baby) in PD1-10.1, and the data was needed in PD1-3.1.

**Outcome:** CMC was able to edit the outgoing message, and now babies are designated as being in NICU or NUR (Nursery) in the HL7 message from CMC.

6. **Determine how NICU information would populate the MTPHL LIMS.** There was no specific field in Copia to populate for NICU or NUR in the demographic information.

**Outcome:** A user-defined field in Copia was designated as the hospital location field on the Demographics page, and the NICU or NUR code was mapped to that field.

7. **Determine process at CMC to transmit and MTPHL to receive birth notification updates.** Birth notification updates may be necessary due to name changes, changes in the attending provider, or other demographic information changes.

**Outcome:** When ADT birth notification messages are updated, they are sent to Copia, designated as ADT (UP) and will overwrite the current demographic information stored in Copia. Changes are stored in the Copia change log.

8. **Determine workflow process at MTPHL to use birth notification data to improve preanalytical aspects of NBS.** This workflow process at MTPHL for using birth notification data is still under development and has yet not been implemented. Receiving birth notification will provide opportunities to give advice to submitting facility to improve quality of pre-analytic NBS. Examples include ensuring that babies in the NICU have a NBS specimen collected prior to treatment, and ensuring timely specimen transport of specimens by the courier by recommending specimen collection times, or making arrangements for transport outside of the routine courier pickup.

**Outcome:** A process map of current NBS Preanalytic activities was drawn (found in Appendix 3), with input from all NBS laboratory staff members at MTPHL. By conducting this review of the
current process, several areas were identified that could be improved by receiving demographic data and test orders electronically, including:

- Numerous re-checks of data on the forms and in Harvest is necessary to assure accuracy, and electronic data should streamline the process.
- Missing essential information currently requires a phone call to CMC to get the data, and electronic data should eliminate missing fields.
- Provider NPI, patient assigned names (not Baby Boy), and birth time are currently manually entered into Harvest, and ideally will be provided electronically, thus eliminating a step.

In addition, new processes to use electronic data were discussed. Once the live birth notification data is in Harvest, review of specimen receipt will be done on a daily basis, and a cut-off time will be established, likely linked to the birth day of the week, for following up on missing specimens. The only matching criteria necessary to match the electronic order from Harvest to the specimen upon receipt will be the form number, and will eliminate the need to completely fill out the form after a period of quality control to assure proper matching of data. Daily review of electronic data including the generation of a daily scheduled report of demographic information and comparison to current quality metrics will be a next step in continuation of the project.

9. **Determine workflow process at CMC to transmit test orders and test order updates.** The existing workflow process at CMC follows: 1) baby is born; 2) live birth is registered in EMR; 3) NBS test is ordered in CMC LIMS; and 4) NBS test order starts the specimen collection process. New options were discussed at CMC and with project partners regarding how to implement an electronic test order system, including coordinating the timing of test orders, determining which tasks are the responsibility of laboratory and nursing personnel, and how certain fields necessary for newborn screening interpretation will be populated.

**Outcome:** CMC created programming for “ask at order entry” (AOE) tests, to include answers to the following questions needed for NBS test interpretation:

- What is the baby’s birthweight?
- Is the baby or mother on antibiotics?
- Is the baby feeding?
- Is the baby or mother on steroids?
- Has the baby received a red cell transfusion and if yes, when?
- Is this a repeat specimen?

These questions will be answered by the phlebotomists in the laboratory after accessing the baby’s charts. Programming was then developed to change AOE results into an electronic update of the test order that was previously sent to MTPHL (see Figures 3, 4, & 5 in Appendix 1).
The workflow process is summarized in Figure 1.

**Figure 1. Order Entry Workflow Process at CMC**

10. **Determine workflow process at MTPHL to receive test orders and test order updates.** Test orders are automatically transferred from Copia into “Release Stored Orders (RSO)” in Harvest, ready for order via the Order Entry Screen. This is the same location where newborn screening forms that are currently scanned for data entry are transferred for release into Harvest.

**Outcome:** Although this step is still in progress, once this process goes “live” the CMC orders will be released using current processes, with the exception that the MTPHL specimen number will be added upon release rather than prior to scanning.
Project Evaluation

The evaluation metrics were calculated for the baseline data, comparing the metrics from all submitters of NBS specimens to the metrics from CMC. The data are listed in Table 2. While most of the metrics for CMC are already better than for the other submitters, there is room for improvement. Due to the time needed in this project for electronic connectivity, there is not yet data available for comparison after receiving electronic birth notification data and implementing subsequent workflow processes.

Table 2. Baseline Data for Evaluation Metrics

<table>
<thead>
<tr>
<th>Measure</th>
<th>All Submitters Baseline</th>
<th>CMC Baseline</th>
<th>CMC Electronic (Pending)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Average time from birth to NBS specimen collection</td>
<td>2.81</td>
<td>2.51</td>
<td></td>
</tr>
<tr>
<td>Average time from collection to receipt at the MTPHL</td>
<td>2.38</td>
<td>2.40</td>
<td></td>
</tr>
<tr>
<td>Percentage of unsatisfactory specimens</td>
<td>1.84%</td>
<td>0.34%</td>
<td></td>
</tr>
<tr>
<td>Number of NBS specimens with missing/inaccurate relevant data</td>
<td>34</td>
<td>3</td>
<td></td>
</tr>
<tr>
<td>Number of corrected or amended NBS reports</td>
<td>3</td>
<td>0</td>
<td></td>
</tr>
</tbody>
</table>

An initial quality assurance project that can be performed prior to going “live” with HL7 data will be to compare the data from the HL7 electronic orders to the data received on the specimen collection forms. The MTPHL is expecting to see improvements in data accuracy due to heightened awareness of the importance of data quality at CMC.

Lessons Learned

- **Improved communication and collaboration.** Weekly calls with project partners and a site visit to CMC to discuss the status and next steps to achieving electronic connectivity resulted in improved communication and collaboration on the project. As with all successful partnerships, we feel like we are friends now in a long-term relationship, and can much more readily work together to continue improvements.

- **Method of message exchange challenges.** Agreement on the message exchange method was time consuming. This project was added on to an already existing interface project which had begun in August 2014, yet there were still delays in connectivity. Cerner is the CMC LIMS, and
delays occurred while project specialists at Cerner were deciding how the bi-directional interface would connect with CMC, and when resources could be assigned to this project. Weekly status calls with project partners during the first 5 months of the interface project (3 months prior to the beginning of this project) were spent on the details of this connectivity process.

- **Lack of easy access to specific data.** This project has highlighted some data accessibility questions in the software. Some data needed for electronic birth notification and test orders is difficult to access in hospital electronic records, for example whether the baby is adopted, on antibiotics, on steroids, or if it is a repeat specimen. Birthweight is not part of the ADT demographic message, and needs to be added with the “ask at order entry” questions. Several attempts at testing transmission of specific fields needed for proper interpretation of NBS results were needed, and are still in progress in order to get all the data fields in the proper format.

- **Need for adjustment of workflow processes.** Modification of some workflow processes is needed at both facilities to accommodate sending and receiving electronic birth notification and test orders. The modifications for sending electronic birth records was done through programming at CMC, including creating the AOE questions, resulting the AOE fields, generating an electronic AOE result message, and converting this result message into an order message. Processes at MTPHL for using the electronic birth records were reviewed as part of this project, and improvements are under development. Clearly, review and update of workflow processes is an important aspect of adding the use of electronic birth data to preanalytical quality improvement.

### Barriers, Concerns, and Other Issues to be Resolved

- **sFTP folder issues.** Using the secure FTP folder for electronic message exchange creates an indirect connection between the two entities. While the sFTP process solves some security concerns, this system may result in delays of data transmissions due to the added complexity of the intermediate step. Because this step is controlled by the IT staff at DPHHS, CMC and MTPHL are not able to view the entire process to be assured messages are not held up. This issue can be resolved by an awareness at MTPHL that lack of data transmission may be caused by a problem in the sFTP folders.

- **Lack of data fields in software.** MTPHL discovered that there is no current field in Copia for both Time of Birth data, NICU, Mother’s Name, and Multiple Birth information. Copia user-defined fields have been created for NICU, Mother’s Name, and Multiple Birth data. Time of Birth is currently a field in Harvest, and this field will be added with the next software update to Copia, currently scheduled for July 2015.

- **Lack of data accessibility in software.** While the birth notification information is present in Copia, it is not easily accessed prior to specimen collection, as the demographic information may be located on multiple screens that are accessed by looking up each birth individually. Most of
the ad hoc reports that can be written in Copia are based on a test order, and the birth notification information is not associated with an order at the time the data is needed. A customized report based on encounter has been developed that can be scheduled to run automatically, but this has not been thoroughly tested to determine if all birth notifications are properly captured.

- **Resource (time, MTPHL IT expertise, and money) issues exist.** Using electronic data exchange for process improvement will require resources that currently do not exist, including time spent in communication of data and transmission needs, and money spent for programming of data exchange. Ideally, use of process mapping will identify areas where some activities can be streamlined to allow the incorporation of additional processes with existing resources.

### Next Steps and Sustainability

- **Use birth notification data to assess effectiveness of pre-analytical procedures and quality improvement processes.** Most of the parts and pieces of birth notification data are successfully in place, including data transmission by CMC, data receipt by MTPHL, and a review of the workflow processes to use the data on a daily basis. Implementation is expected to occur in the next 3 months.

- **Continue with electronic connectivity project with CMC to include real-time test ordering and test reporting.** This is a mutually beneficial project, as both CMC and MTPHL want to complete the project to enhance patient safety by:
  - Use birth notification data to improve pre-analytical quality
  - Use real-time test ordering to improve data accuracy and turn-around time
  - Use real-time test reporting to reduce the time and effort needed to get results to the healthcare provider and reduce transcription errors

- **Expand electronic connectivity project to Billings Clinic.** CMC began a new partnership in January 2015, following completion of the hospital’s sale to a joint venture between Billings Clinic and Regional Care Hospital Partners. Billings Clinic is a large hospital system in Montana, also providing about 15% of the births in Montana. Since they are co-owned and use Cerner as the same LIMS, the CMC process has been designed to also work with processes in place at Billings Clinic. We anticipate reaching out to them next to work with MTPHL on electronic connectivity.

- **Expand birth notification process improvement to other Montana birth hospitals, and HL7 connectivity for orders and results (OE/RR) for their laboratories, once complete data is available from pilot project.** It is expected that once the birth notification process improvement, along with OE/RR, is completed with two facilities that together comprise 30% of the births in Montana, other laboratories will want to join in on electronic connectivity. Although resource issues (lack of time, MTPHL IT expertise, and money) will likely exist, ideally a cost savings can be demonstrated by reducing staff time and transcription errors.
Gaps in the Overall Project

- **Time.** The short 5-month time frame of this project limited the scope of the achievable goals. We expect it will take at least a year, working with our project partners, to accomplish the original goals outlined in the proposal. Because some of our partners (the programmers and laboratory staff at CMC) are outside of our span of control, they had other priorities which sometimes took them away from working on this project.

- **Vendor programming.** Some project limitations are due to lack of specific LIMS programming by the respective vendors at CMC (Cerner) and at MTPHL (Orchard). Examples of specific programming needed are processing of inbound test results by Cerner, and time of birth data in Copia by Orchard. This also is outside of our control, as vendors have their priorities set by the major entities paying for their service and support. This project is not yet high on their list for programming support.

**Conclusion:**
The MTPHL expended all of the funds received for this project for project management, interface and programming costs, IT Connectivity and IT Specialist costs, and administrative costs. MTPHL appreciates the opportunity to participate in this proof of concept project to determine whether the receipt of electronic birth notification data could positively impact pre-analytical processes in newborn screening. Although there were challenges, and the project was not completed in the time allotted, many positive results were achieved. MTPHL looks forward to the full implementation of this project as an enhancement to our continuous efforts to improve accuracy and timeliness in newborn screening.
Appendix 1: Examples of Birth Notification Data

Figure 1: Baby demographic data in Copia, test message sent from CMC
Figure 2: HL7 Message of ADT data in Copia
Figure 3: Ask at Order Entry (AOE) Questions at CMC

<table>
<thead>
<tr>
<th>Selection</th>
<th>Demographics</th>
</tr>
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<tbody>
<tr>
<td>Accession: 15-181-0006</td>
<td>Patient Name: CMCMTEST, STATELAB</td>
</tr>
<tr>
<td>Procedure: All</td>
<td>DOB: 08/08/1971</td>
</tr>
<tr>
<td>Test Site: All</td>
<td>Age: 43 years</td>
</tr>
<tr>
<td></td>
<td>Gender: FEMALE</td>
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</table>

<table>
<thead>
<tr>
<th>Procedure</th>
<th>Result</th>
<th>Range</th>
<th>Status</th>
<th>Reference Rang</th>
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<tbody>
<tr>
<td>Biotinidase</td>
<td></td>
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<td>Pending</td>
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</tr>
<tr>
<td>17-Hydroxyprogesterone (CAH)</td>
<td></td>
<td></td>
<td>Pending</td>
<td></td>
</tr>
<tr>
<td>Immuno-os Trypsinogen (CF)</td>
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<td></td>
<td>Pending</td>
<td></td>
</tr>
<tr>
<td>Fatty Acid Oxid</td>
<td></td>
<td></td>
<td>Pending</td>
<td></td>
</tr>
<tr>
<td>Galactose, PKU</td>
<td></td>
<td></td>
<td>Pending</td>
<td></td>
</tr>
<tr>
<td>Hemoglobinopathy Screen</td>
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</tr>
<tr>
<td>Leucine (MSUD)</td>
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<tr>
<td>Methionine (MCT)</td>
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<td>Citrulline (CT/ASA)</td>
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<td>Tyrosine (TYR)</td>
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<td>Thyroxine, PKU</td>
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<tr>
<td>TSH, PKU</td>
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<td></td>
<td></td>
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<td>Repeat Specimen?</td>
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</tr>
<tr>
<td>Mother/Infant on Antibiotics?</td>
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<td>Pending</td>
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<tr>
<td>Adopted?</td>
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<td>Pending</td>
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<tr>
<td>Baby rec’d a transfusion?</td>
<td>✔</td>
<td>No</td>
<td>Pending</td>
<td></td>
</tr>
<tr>
<td>Date of Transfusion</td>
<td>✔</td>
<td>Not Applicable</td>
<td>Pending</td>
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</tbody>
</table>
Figure 4: HL7 Order Update Message with AOE Questions in Copia

Message Detail: ZZOMCMTEST, STATELAB

Message Type: HL7

Number of Attempts: 1
Cursor Position:
Cursor Line: Column:

Successfully parsed inbound message.

Translated Message show

Mapper Script show

This popup will automatically resize when using the sliders

Save  Run Mapper  Close
Figure 5: Data Contents of HL7 test message sent from CMC to MTPHL

**Message Header**

| MSH | ^~\& | CERNER | COMMUNITYMEDICALCENTER | ORCHARD | MTPHL | 20150703113234 | ORM^O01 | Q10186358 50T1119716606 | P | 2.3 |

**Patient Identification**

| PID | 1 | 9577064 | ZZCMCMTEST^STATELAB | 19710808 | F | U | address line 1^Lolo^MT^59847^USA | (406)000-0000^Home | M | Baptist | 80312694 | 112000000 |

**Patient Visit**

| PV1 | 1 | O | LAB OP^^^&CMC | R | 1659403038^Fausett^M Bardett | LAB | 1659403038^Fausett^M Bardett | OP | 20150616085504 |

**Common Order**

| ORC | XO | 1555914473^HNAM_ORDERID | OBR | 1 | 1555914473^HNAM_ORDERID | NBS | 2 | 20150703112100 | 20150703112200 | Blood&Blood^^^^^Capillary | 20150703113230 | 20150703113230 |

**Lab Order**

| OBX | 1 | CE | N Antibiotics^Mother/Infant on Antibiotics? | No | ? | Unknown | F | 20150703113227 | ^Church^Alwin |

| OBX | 2 | CE | N 24^Baby >24 Hours old at collection? | Yes | ? | Unknown | F | 20150703113227 | ^Church^Alwin |

| OBX | 3 | NUM | NBSForm^NBS Form Number | 33333333 | ? | Unknown | F | 20150703113227 | ^Church^Alwin |

| OBX | 4 | CE | N FeedMethod^Feeding Method | Formula, Soy | ? | Unknown | F | 20150703113227 | ^Church^Alwin |

| OBX | 5 | CE | N Transfus2^Baby rec'd a transfusion? | No | ? | Unknown | F | 20150703113227 | ^Church^Alwin |

| OBX | 6 | CE | N Other^Adopted? | No | ? | Unknown | F | 20150703113227 | ^Church^Alwin |

| OBX | 7 | CE | N Steroids^Mother/Infant on Steroids? | No | ? | Unknown | F | 20150703113227 | ^Church^Alwin |

| OBX | 8 | CE | N Repeat^Repeat Specimen? | No | ? | Unknown | F | 20150703113227 | ^Church^Alwin |

| OBX | 9 | CE | N DateofTrans2^Date of Transfusion | Not Applicable | ? | Unknown | F | 20150703113227 | ^Church^Alwin |
Appendix 2: Example of NBS Quality Report Card

State of Montana
Department of Health and Human Services
Newborn Screening

Birth Hospital

Montana Public Health Laboratory Quality Assurance Report (Quarter 1)

<table>
<thead>
<tr>
<th>Number of Specimens Received</th>
<th>Q1</th>
<th>Q2</th>
<th>Q3</th>
<th>Q4</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of Total Screening Specimens:</td>
<td>381</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Number of Initial Screening Specimens:</td>
<td>350</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Number of Unsatisfactory Screening Specimens:</td>
<td>1</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Age (in hours) at Initial Specimen Collection

<table>
<thead>
<tr>
<th>Period at a Glance:</th>
</tr>
</thead>
<tbody>
<tr>
<td>96.00%</td>
</tr>
</tbody>
</table>

% Initial specimens collected within recommended 24 to 48 hours of age.

Days Between Specimen Collection and Receipt

<table>
<thead>
<tr>
<th>Period at a Glance:</th>
</tr>
</thead>
<tbody>
<tr>
<td>82.68%</td>
</tr>
</tbody>
</table>

% Specimens received within 3 days after collection.

Days Between Specimen Receipt and Approved Result

<table>
<thead>
<tr>
<th>Period at a Glance:</th>
</tr>
</thead>
<tbody>
<tr>
<td>59.84%</td>
</tr>
</tbody>
</table>

% Specimens resulted within 3 days after receipt.

If you have any questions regarding this Quality Assurance Report, please contact:
The Montana Newborn Screening Laboratory (406) 444-0584
# Montana Public Health Laboratory Quality Assurance Report (Quarter 1)

This facility report card is being sent to each Montana birthing facility as an aid to help track and improve newborn screening turnaround times. Each step in the process to produce a newborn screening result is being tracked, as well as unsatisfactory specimens and missing or incorrect information which both cause substantial delays.

## Unsatisfactory Specimens

The goal of our program is to reduce unsatisfactory specimens to a theoretical goal of zero. There are many reasons that a specimen can be classified as an unsatisfactory specimen, the most common being insufficient specimen to completely fill the circle on both sides of the filter paper, overlaying sample where several drops are applied on top each other with partial drying in between each application, and abrasion by capillary tubes or bending of the spots during transport.

Please phone our facility for educational materials to aid your staff in collecting adequate specimens. An adequate specimen is one in which the concentration of blood in all parts of the circle is consistent.

If in doubt of the adequacy of a specimen please collect a second sample immediately, to avoid delays in obtaining a newborn screening report for that infant.

## Age at Initial Specimen Collection

According to the revised Montana Administrative Rule 37.57.305 effective July 1, 2014 initial specimens should be collected between 24 and 48 hours of age unless the infant is hospitalized for neonatal intensive care and there are medical contraindications.

## Days Between Specimen Collection and Receipt at Montana Public Health Laboratory

It is crucial that newborn screening blood spots are either mailed or sent by courier as soon as possible and are not batched. If you are having problems with delivery times we would welcome the opportunity to consult with you to try and determine a more time effective transport method.

## Missing Information

In order to facilitate follow up of out of range results we need the newborn card completed in full and with In order to facilitate follow up of out of range results we need the newborn card completed in full and with correct information. There are several providers within the State and even in the same town with identical last names. Please list the provider's first name or initial to prevent confusion. If possible please provide the correct NPI number also.

Each time there is missing information we have to phone the facility to obtain it. Often we are transferred to several numbers before we can obtain an answer. This involves time for our clinical scientists and your staff that could be put to much better use. Please review the cards before sending to check for missing or incorrect information.

## Days Between Receipt at Montana PHL and Result for Out of Range Results

Our goal is to provide all screening results within as short a time as possible. All out of range results are faxed to facilities, and those that require actions to be taken are phoned to providers.

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If you have any questions regarding this Quality Assurance Report, please contact:  
The Montana Newborn Screening Laboratory (406) 444-0584
Appendix 3: Process Mapping Worksheets

Preanalytical Specimen Collection and Transport (CMC)

- NBS specimen cards provided to CMC
- CMC stores cards
- Baby born → test ordered → specimen collected by lab staff in NURS or NICU
- ADT message to M+PHL
- ADT update and AOE message sent to M+PHL
- Store specimen for courier pickup at 2pm
- Print daily demographic report
- Labels printed + form filled out
- Dry specimen
Specimen Review and Accessioning (MTPHL)

NBS Specimen Review & Accessioning delivered via courier
in mailroom → sort NBS specimens by submitter → repeat for NBS specimen delivered via mail
in lab → review specimen and data quality

- satisfactory
  → add bar code label to card & form
  → specimen dual check
  → testing

- unsatisfactory
  → call for missing info & report of unsat
  → unsats to Excel list for expected repeats

Accessioning process
  → scan forms in batches of 20
  → verify data (next page)
Data Entry including Verification of Data

Verifying Data in Harvest

- Check data accuracy in Teleform
  - Correct scanned info as needed
  - Make phone calls for data as needed
- In Harvest
- Transfer data
- In Access + Excel
- Release stored orders (check data accuracy)
- Check data accuracy and correct as needed
- Referral process to WI
- Enter provider name if missing NPI
- Enter birth time

- Check data accuracy on Mondays
- Scan and verify data on Saturdays
- Change receive date to Set
- Send to WI