



GDSP Health Information Exchange Program Overview



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Project Overview

Overview: This objective of this project is to extend the functionality of the State of CA's Screening Information System application to provide Newborn Screening Test Results electronically in HL7 format for providers.

Overall, the project is intended to:

- **Provide an efficient solution for transmitting newborn screening results** to hospitals and clinicians, and move away from paper-based manual processes
- **Meet the goal of “Meaningful Use” for HIE** since paper exchange does not conform to federal incentives toward EHR adoption and “Meaningful Use” of these systems. Providers have strong incentives to move away from paper as soon as possible.

National Standards: The file format defined for the file transmission follows national standards established for the electronic transmission of NBS results, derived from the following sources:

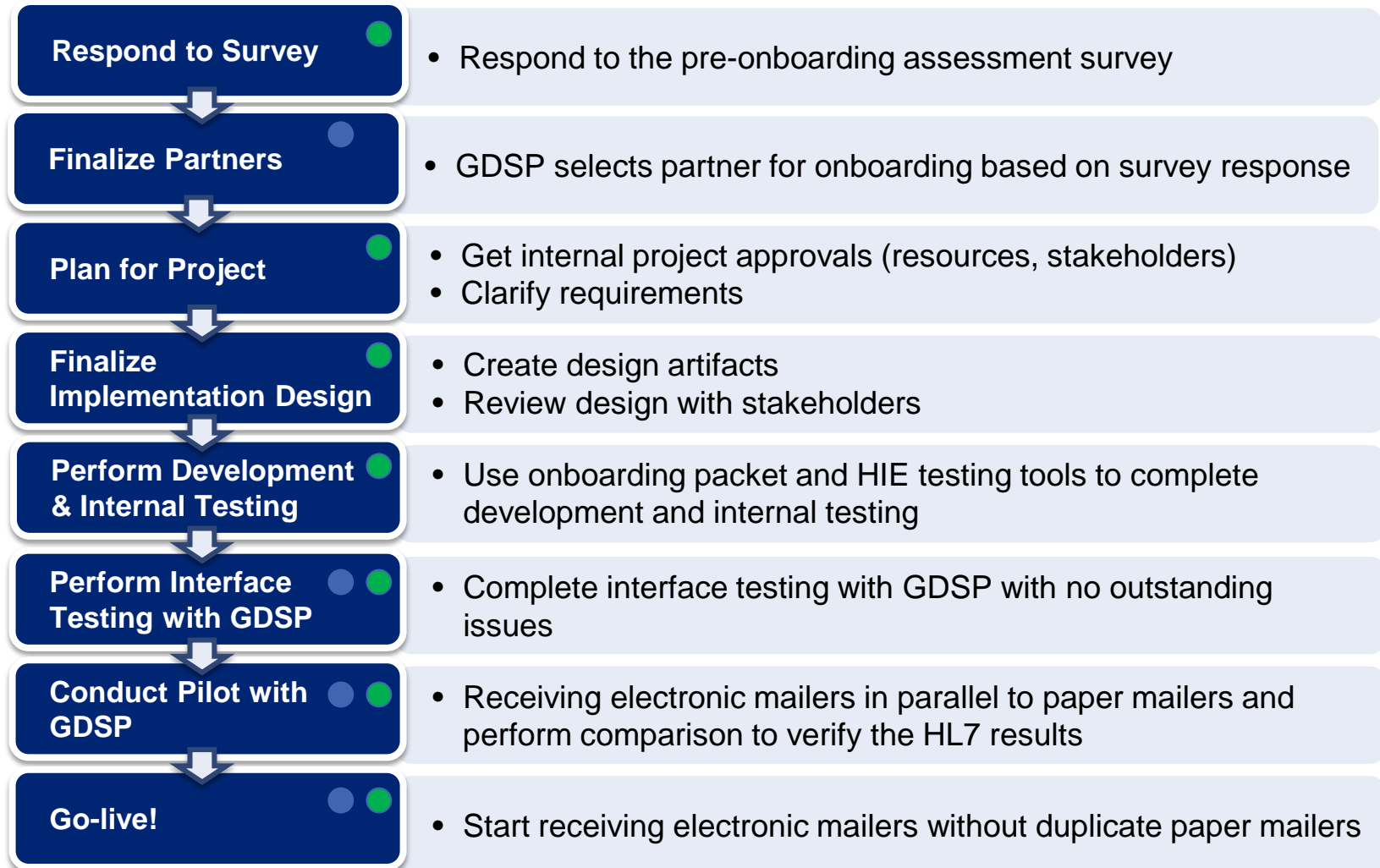
- Format standards from the “HITSP Newborn Screening Interoperability Specification”*
- Content standards from the “Newborn Screening Coding and Terminology Guide” published by the National Library of Medicine
- SIS will use the Logical Observation Identifiers Names and Codes (LOINC)** to communicate the analytes, laboratory observations & diagnostic information
 - In cases where no LOINC code currently exists, a local code is proposed
- NBS test results message will follow HL7 version 2.5.1 messaging format, recommended by Cal eConnect
- SIS will use the HIPAA compliant and state approved secure FTP protocol for transferring the NBS test results messages to the providers

* HITSP is the Health Information Technology Standards Panel

** LOINC provide a set of universal codes and names to identify analytes, laboratory observations and diagnostic information

Partner On-boarding Steps

Following steps needs to be completed by hospital for onboarding hospitals to receive NBS results electronically using HL7 standards.

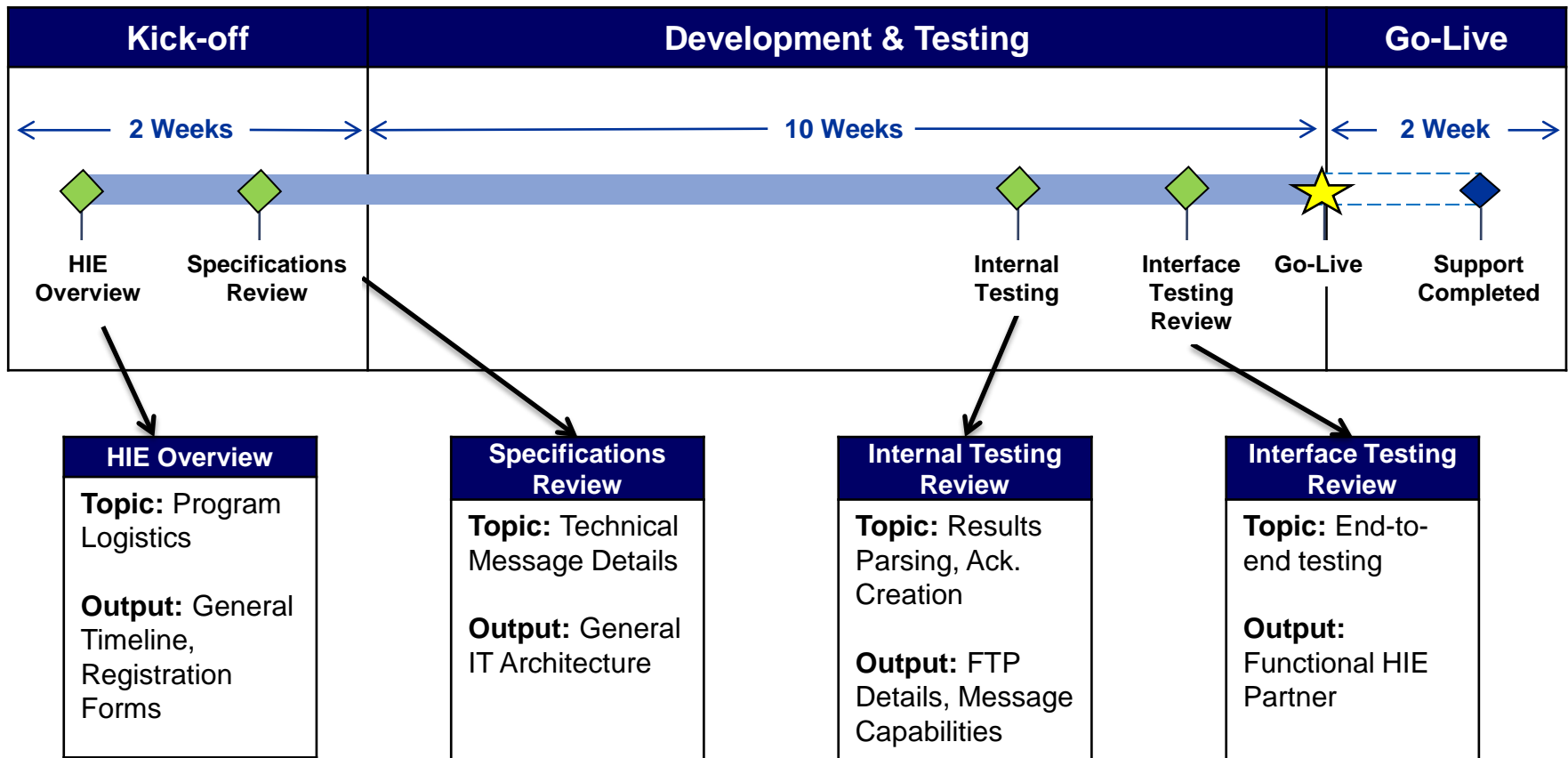


● GDSP ● HIE Partner

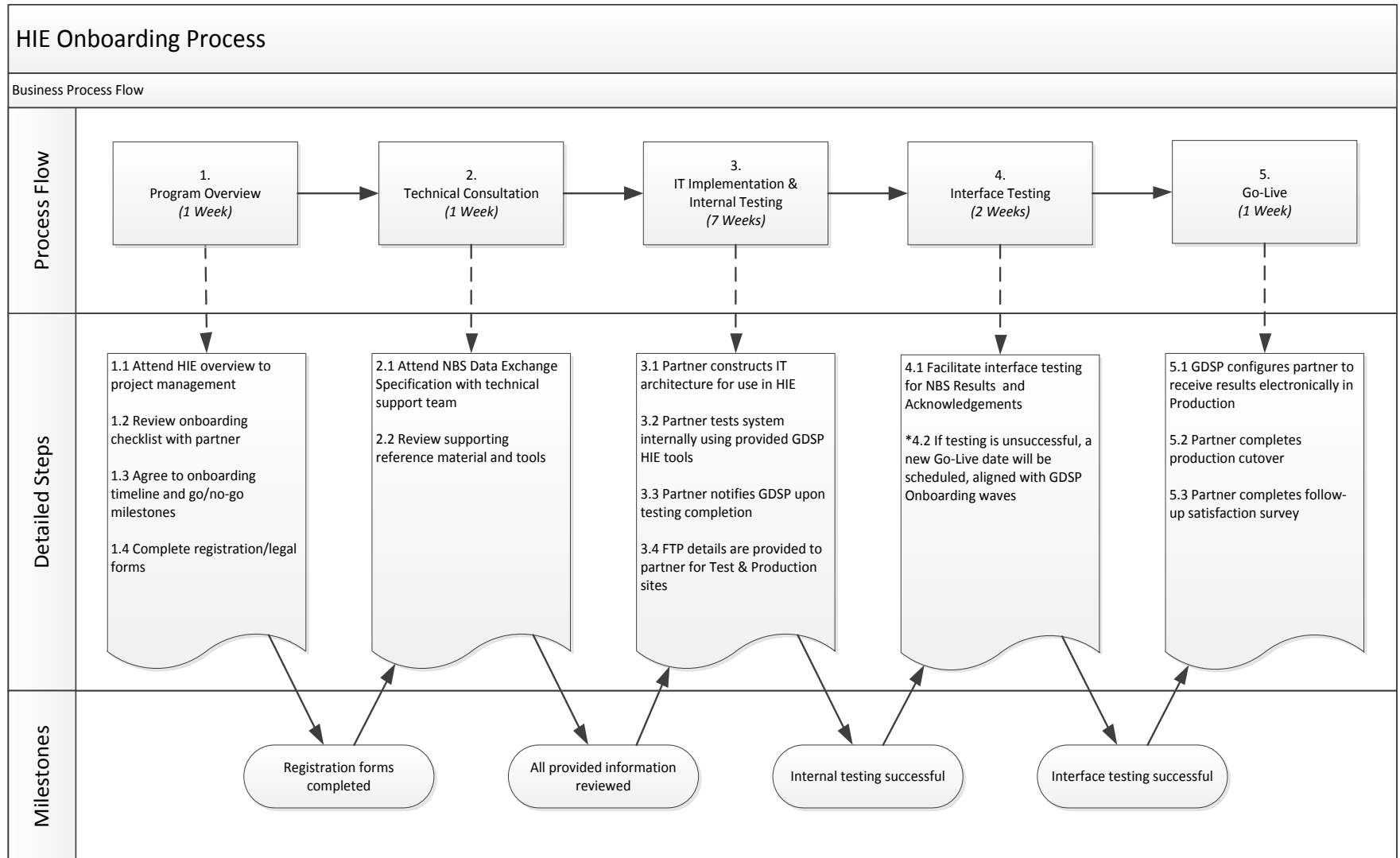
HIE Implementation Schedule

Partner onboarding follows a three step approach:

1. **Kick-Off:** Review GDSP HIE program and message specifications
2. **Development & Testing:** Necessary IT architecture is developed and tested
3. **Go-Live:** Functioning system is deployed to a production environment



HIE Onboarding Process





HIE Receivers & Forms

HIE Receivers are organizations that will accept the responsibility to receive and parse electronic results.

To participate in the GDSP HIE project, an HIE Receiver must complete the following forms:

No.	Form	Description
1	GDSP NBS Participation Agreement	Ensures HIE receiver agrees to review all necessary material, undergo necessary training, etc.
2	Hospitals/Health Practice Management Firm (HPM) Enrollment, Update, and Removal Form	A form for hospitals/HPM to enroll for GDSP HIE project and receive results electronically
3	Health Information Exchange (HIE) of Electronic Screening Results Business Associate Agreement	Business Agreement form between GDSP and Hospital/HPM to receive results electronically in accordance to HIPAA

HL7 Message Format

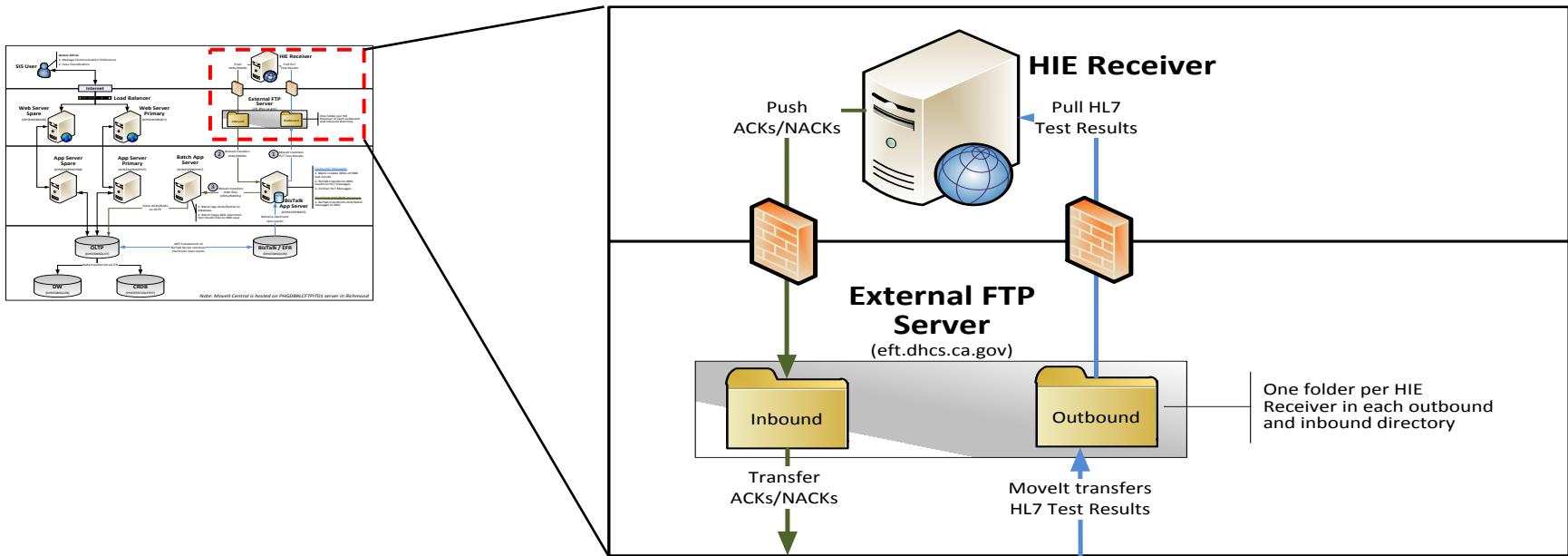
Below are key details regarding the HL7 message format:

- **HL7 Version:** HL7 v2.5.1
- **Standard:** Public Health Informatics Institute (PHII) and U.S. National Library of Medicine (NLM)
 - PHII website: <http://www.phii.org/>
 - NLM website: <http://newbornscreeningcodes.nlm.nih.gov/nb/sc/constructingNBShl7messages>
- **Medium:** Secure File Transfer Protocol through an external server
Note: Each HIE Receiver will have a dedicated folder, for both the Inbound and the Outbound Directory
- **Frequency:** Daily, excluding Saturdays and State Holidays
- **File Format:** HL7 messages to be zipped and place on both Inbound and Outbound Directory of secure FTP server

Below are details for each message type (Newborn Screening results & Acknowledgement/Error message):

- **Newborn Screening Results:**
 - **Message Type:** ORU^R01 (Results)
 - **Timing:** Electronic Test Results will be placed in respective Outbound directories at **9:00 PM PST**
- **Acknowledgments / Error Messages:**
 - **Message Type:** ACK^R01^ACK (Acknowledgments)
 - **Timing:** ACK messages should be placed in respective Inbound directories by **4:00 AM PST**

Data Transmission Flow



Sending Newborn Screening Results to HIE Partner:

1. SIS GDSP will place NBS results in HL7 v.2.5.1 messages in a **zip file**, in a specified folder, on the Outbound directory of the secure FTP server
2. HIE Partner will **pull** the zipped HL7 messages from the secure FTP server and unzip them for HL7 message translation
3. HIE Partner will **translate** the HL7 messages for data processing

Receiving Acknowledgments (ACK) and Error (NACK) messages at SIS GDSP:

1. HIE Partner will **create ACK / NACK HL7 messages** for each NBS result message it processes
2. HIE Partner will **zip the ACK/NACK messages** and **push** the zipped file to a specified folder in the Inbound directory of the secure FTP server
3. SIS GDSP will **translate** the ACK/NACK messages from the secure FTP server for processing

Next Steps and Contact Information

- Requirement session participants should have already received meeting invitations
- Requirement sessions are scheduled through Wed, 01/23 including a Parking Lot session which will be held only if needed

Key Contacts:

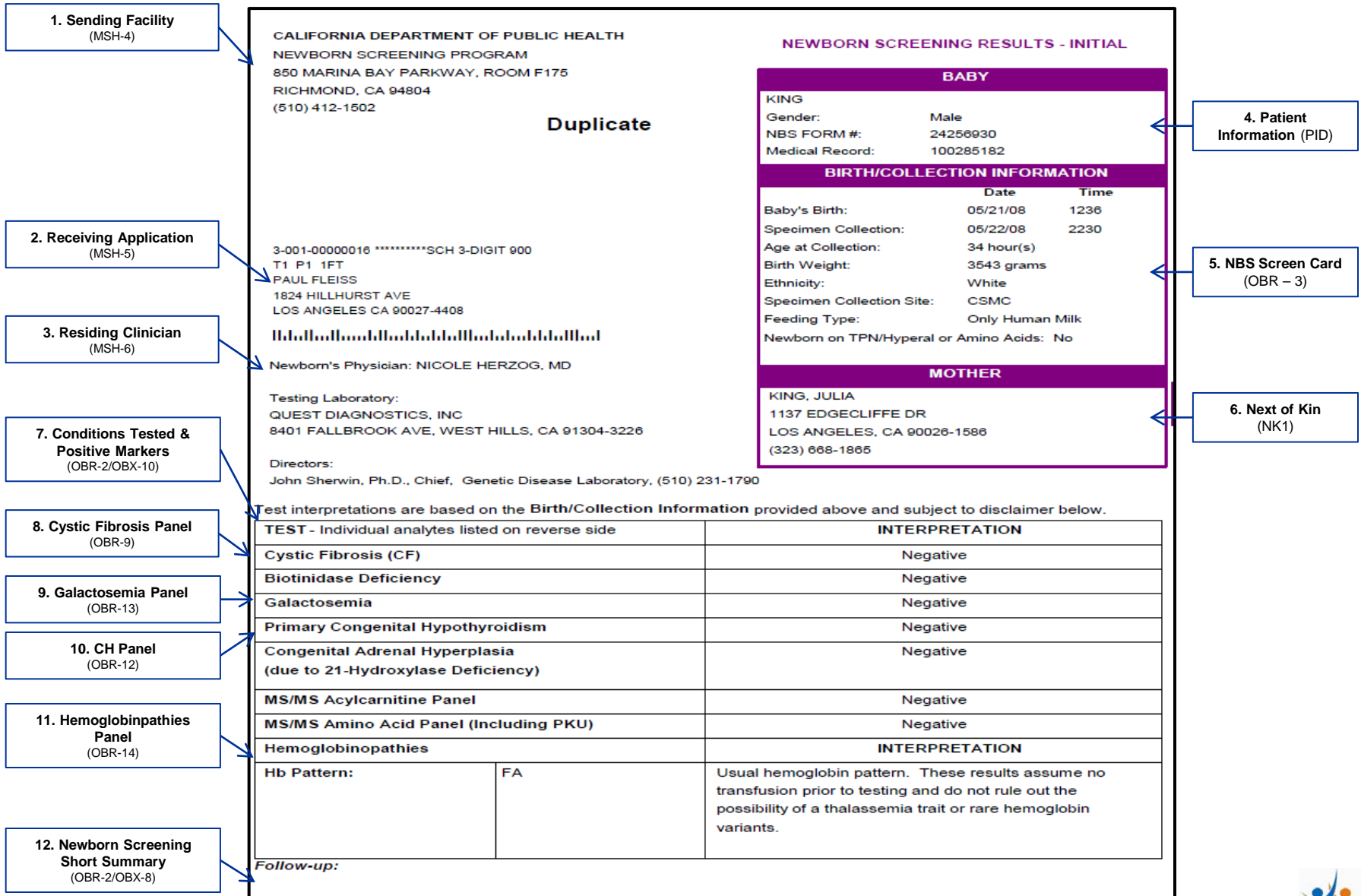
- GDSP – Carole Klein Carole.Klein@cdph.ca.gov
- GDSP – Robin Thomas robin.thomas@cdph.ca.gov
- Functional Lead – Swapnil Pradhan spradhan@deloitte.com
- Application Manager – Raja Antony rsdantony@deloitte.com

Appendix

Key Terms and Acronyms

- **SIS:** State of CA's Screening Information System application
- **HITECH:** Health Information Technology for Economic and Clinical Health
- **Meaningful Use Standards:** Set of objectives and measures to encourage the actual “meaningful use” of HIT, not just purchase and installation
- **HL7:** Health Level 7 messaging standard that enables clinical applications to exchange data; “book of rules” detailing interfacing information that sets forth a framework for negotiation in interfacing
- Coding Systems
 - **LOINC** – Logical Observation Identifiers Names and Codes (LOINC®): provides standardized codes for the questions in lab results messages; used for ordering and resulting of lab tests; preferred code set for HL7 messages
 - **CPT** – used for ordering and billing purposes; not as specific as LOINC codes
 - **SNOMED** – Standardized terminology for clinical data for diseases, clinical findings and procedures
- **Health Information Technology Standards Panel (HITSP) Newborn Screening Interoperability Specification:** messaging standards specific to NBS

HL7 Message Structure: PDF Mailer to HL7 High-Level Mapping (1 of 3)



CALIFORNIA DEPARTMENT OF PUBLIC HEALTH
 NEWBORN SCREENING PROGRAM
 850 MARINA BAY PARKWAY, ROOM F175
 RICHMOND, CA 94804
 (510) 412-1502

Duplicate

3-001-00000016 *****SCH 3-DIGIT 900
 T1 P1 1FT
 PAUL FLEISS
 1824 HILLHURST AVE
 LOS ANGELES CA 90027-4408

|||||
 Newborn's Physician: NICOLE HERZOG, MD

Testing Laboratory:
 QUEST DIAGNOSTICS, INC
 8401 FALLBROOK AVE, WEST HILLS, CA 91304-3226

Directors:
 John Sherwin, Ph.D., Chief, Genetic Disease Laboratory, (510) 231-1790

Test interpretations are based on the Birth/Collection Information provided above and subject to disclaimer below.

TEST - Individual analytes listed on reverse side	INTERPRETATION
Cystic Fibrosis (CF)	Negative
Biotinidase Deficiency	Negative
Galactosemia	Negative
Primary Congenital Hypothyroidism	Negative
Congenital Adrenal Hyperplasia (due to 21-Hydroxylase Deficiency)	Negative
MS/MS Acylcarnitine Panel	Negative
MS/MS Amino Acid Panel (Including PKU)	Negative
Hemoglobinopathies	INTERPRETATION
Hb Pattern: FA	Usual hemoglobin pattern. These results assume no transfusion prior to testing and do not rule out the possibility of a thalassemia trait or rare hemoglobin variants.

Follow-up:

NEWBORN SCREENING RESULTS - INITIAL

BABY

KING
 Gender: Male
 NBS FORM #: 24250930
 Medical Record: 100285182

BIRTH/COLLECTION INFORMATION

	Date	Time
Baby's Birth:	05/21/08	1236
Specimen Collection:	05/22/08	2230
Age at Collection:	34 hour(s)	
Birth Weight:	3543 grams	
Ethnicity:	White	
Specimen Collection Site:	CSMC	
Feeding Type:	Only Human Milk	
Newborn on TPN/Hyperal or Amino Acids:	No	

MOTHER

KING, JULIA
 1137 EDGECLIFFE DR
 LOS ANGELES, CA 90026-1586
 (323) 668-1865

HL7 Message Structure: PDF Mailer to HL7 High-Level Mapping (2 of 3)

13. Acylcarnitine Panel / Fatty & Organic Acids (OBR-6/OBR-7/OBR-8)

14. Amino Acid Panel (OBR-5)

15. CAH Panel (OBR-11)

16. SCID Panel (OBR-15)

Acylcarnitine Panel			
C-8	< 0.8 µmol/L	0.080 µmol/L	
C8/C10 Ratio		1.33	
C-8:1	< 0.7 µmol/L	0.210 µmol/L	
C-10	< 0.85 µmol/L	0.080 µmol/L	
C-10:1	< 0.45 µmol/L	0.080 µmol/L	
C-12	< 2 µmol/L	0.080 µmol/L	
C-12:1		0.05 µmol/L	
C-14	< 1.2 µmol/L	0.310 µmol/L	
C14:1	< 0.8 µmol/L	0.120 µmol/L	
C14:1 / C12:1 Ratio		2.40	
C14:2		0.05 µmol/L	
C-14:OH	< 0.2 µmol/L	0.020 µmol/L	
C-16	< 1.0 µmol/L	0.280 µmol/L	
C-16:1	< 1.4 µmol/L	0.370 µmol/L	
C-16:OH	< 0.1 µmol/L	0.020 µmol/L	
C16:OH / C16 Ratio	< 0.07	0.00476	
C-18	< 4 µmol/L	1.070 µmol/L	
C-18:1	< 7 µmol/L	2.180 µmol/L	
C-18:2		0.73 µmol/L	
C-18:OH	< 0.1 µmol/L	0.020 µmol/L	
C-18:1:OH	< 0.1 µmol/L	0.020 µmol/L	
Amino Acid	Reference Range	Result	Flag
Serine		543 µmol/L	
Alanine	< 1000 µmol/L	364 µmol/L	
Valine		304.8 µmol/L	
Valine / Phenylalanine Ratio	< 3.5	2.36811	
Leucine/Isoleucine	< 250 µmol/L	262.4 µmol/L	High
Leucine/Alanine Ratio	< 1.3	0.80	
Phenylalanine	< 155 µmol/L	137.1 µmol/L	
Phenylalanine/Tyrosine Ratio	< 1.5	0.84	
Tyrosine	< 850 µmol/L	159.8 µmol/L	
Succinylacetone	< 3 µmol/L	0.56 µmol/L	
Methionine	> 8 to < 100 µmol/L	85 µmol/L	
Citrulline	> 5 to < 85 µmol/L	16 µmol/L	
Citrulline/Arginine Ratio		0.24	
Ornithine	< 600 µmol/L	188 µmol/L	
Ornithine/Citrulline Ratio		8.72	
Arginine	< 250 µmol/L	80 µmol/L	
Arginine/Ornithine Ratio		0.43	
Proline	< 1500 µmol/L	265 µmol/L	
5-Oxoproline		43 µmol/L	
Analyte	Reference Range	Result	Flag
Immunoreactive Thyroglobulin	< 60 ng/mL	6.74 ng/mL	
Biotinidase	> 10 nIU	30.88 nIU	
Galactose-4-epimerase	> 50 enzyme units	221.13 enzyme units	
TSH	< 25 mIU/L	3.26 mIU/L	
17-Hydroxyprogesterone (17-OHP)	< 38 nmol/L	19.82 nmol/L	
Cortisol		36.07 nmol/L	
Androstenedione		8.58 nmol/L	
(17-OHP)/Androstenedione/Cortisol Ratio	< 1	1.01	High

Screen for CAH based on 17-ORP level and a steroid ratio level.

HL7 Message Structure: HL7 Sample Message (3 of 3)

Below is a sample HL7 message for SIS GDSP newborn screening initial negative test results

```

MSH|^~\&|SIS|NBS 850 MARINA BAY|||201103171117||ORU^R01|1234567890|T|2.5.1|||CALIFORNIA DEPARTMENT OF PUBLIC HEALTH
PID|1||924250^48011183^189-52-123/21-2010-72||Sung|labrb^Amethyst||201103171117|Male|other Race||
NK1|1|Bourne^Julia|Mother|427 4th Street^New York^NY ^94782|9163720117|||
ORC|RE|||||ZZSmith,Nicole - MD|||||R150-UCLA Medical Center
OBR|1||9952580682|54089-8^Newborn screening panel American Health Information Community (AHIC) ^LN||20110525|||||201105251200|FLT|||||
OBR|1||9952580682|57128-1^Newborn Screening Report summary panel ^LN||20110525|||||201105251200|FLT|||||
OBX|1|CE|57721-3^Reason for lab test in Dried blood spot ^LN|1|LA12421-6 (Initial screen)|||F|||25052011|||||
OBX|2|CE|57718-9^Sample quality of Dried blood spot ^LN|1|LA12432-3 (Acceptable)|||F|||25052011|||||
OBX|3|CE|57130-7^New born screening report - overall interpretation ^LN|1|LA6626-1 (Normal)|||A|||F|||25052011|||||
OBX|4|CE|57131-5^Newborn conditions with positive markers [Identifier] in Dried blood spot ^LN|1|LA137-2 (none)|||A|||F|||25052011|||||
OBX|5|CE|57720-5^Newborn conditions with equivocal markers [Identifier] in Dried blood spot ^LN|1|LA137-2 (none)|||N|||F|||25052011|||||
OBX|6|FT|57724-7^Newborn screening short narrative summary ^LN|1|FOLLOW UP: /TESTING LABORATORY: QUEST DIAGNOSTICS, INC 8401 FALLBROOK AVE
Genetic Disease Laboratory, (510) 231-1790/DISCLAIMER: Due to biological variability of newborns and differences in detection rates for th
Program will not identify all newborns with these conditions. While a positive screening result identifies newborns at an increased risk t
rule out the possibility of a disorder. Health care providers should remain watchful for any sign or symptoms of these disorders in their
diagnostic, and cannot replace the individualized evaluation and diagnosis of an infant by a well-trained, knowledgeable health care provi
the Newborn Screening staff at UCLA Medical Center, (310) 826-4458.|||||F|||25052011|||||
OBX|7|TX|57129-9^Full newborn screening summary report for display or printing ^LN|1|This is sample text|||||F|||25052011|||||
OBX|8|CE|57719-7^Conditions tested for in this NBS study^LN|1|LA12915-7 (3-MCC or 3-MCC (mat) 3MGA or BKT or HMG or MCD or BIO)|||A|||F|||
OBX|9|CE|57719-7^Conditions tested for in this NBS study^LN|1|LA12469-5 (5-OXO)|||A|||F|||20090714143552
OBX|10|CE|57719-7^Conditions tested for in this NBS study^LN|1|LA12537-9 (CF)|||A|||F|||20090714143552
OBX|11|CE|57719-7^Conditions tested for in this NBS study^LN|1|LA12487-7 (CUD)|||A|||F|||20090714143552
OBX|12|CE|57719-7^Conditions tested for in this NBS study^LN|1|LA12497-6 (HHH)|||A|||F|||20090714143552
OBX|13|CE|57719-7^Conditions tested for in this NBS study^LN|1|LA12521-3 (PRO I)|||A|||F|||20090714143552
OBX|14|CE|57719-7^Conditions tested for in this NBS study^LN|1|LA12574-2 (LCHAD or TFP)|||A|||F|||20090714143552
OBX|15|CE|57719-7^Conditions tested for in this NBS study^LN|1|LA12508-0 (MAL)|||A|||F|||20090714143552
OBX|16|CE|57719-7^Conditions tested for in this NBS study^LN|1|LA12509-8 (MCAD)|||A|||F|||20090714143552
OBX|17|CE|57719-7^Conditions tested for in this NBS study^LN|1|LA12510-6 (MCD)|||A|||F|||20090714143552
OBX|18|CE|57719-7^Conditions tested for in this NBS study^LN|1|LA12516-3 (NKHG)|||A|||F|||20090714143552
OBX|19|CE|57719-7^Conditions tested for in this NBS study^LN|1|LA12520-5 (PKU)|||A|||F|||20090714143552
OBX|20|CE|57719-7^Conditions tested for in this NBS study^LN|1|LA12524-7 (SCAD)|||A|||F|||20090714143552
OBX|21|CE|57719-7^Conditions tested for in this NBS study^LN|1|LA12543-7 (GALT)|||A|||F|||20090714143552
OBX|22|CE|57719-7^Conditions tested for in this NBS study^LN|1|LA12572-6 (TYR-I or TYR-II or TYR-III)|||A|||F|||20090714143552
OBX|23|CE|57719-7^Conditions tested for in this NBS study^LN|1|LA12531-2 (VLCAD)|||A|||F|||20090714143552
OBX|24|CE|57719-7^Conditions tested for in this NBS study^LN|1|LA12470-3 (ARG)|||A|||F|||20090714143552
OBX|25|CE|57719-7^Conditions tested for in this NBS study^LN|1|LA12532-0 (BIO)|||A|||F|||20090714143552
OBX|26|CE|57719-7^Conditions tested for in this NBS study^LN|1|LA12474-5 (BKT)|||A|||F|||20090714143552
OBX|27|CE|57719-7^Conditions tested for in this NBS study^LN|1|LA12533-8 (CAH)|||A|||F|||20090714143552
OBX|28|CE|57719-7^Conditions tested for in this NBS study^LN|1|LA12537-9 (CF)|||A|||F|||20090714143552
OBX|29|CE|57719-7^Conditions tested for in this NBS study^LN|1|LA12569-2 (CIT-I or CIT-II or ASA)|||A|||F|||20090714143552
OBX|30|CE|57719-7^Conditions tested for in this NBS study^LN|1|LA12485-1 (CPT-Ia)|||A|||F|||20090714143552
OBX|31|CE|57719-7^Conditions tested for in this NBS study^LN|1|LA12493-5 (GA-1)|||A|||F|||20090714143552
OBX|32|CE|57719-7^Conditions tested for in this NBS study^LN|1|LA124495-0 (GA-2)|||A|||F|||20090714143552
OBX|33|CE|57719-7^Conditions tested for in this NBS study^LN|1|LA12570-0 (HCY or MET or CBL C)|||A|||F|||20090714143552
OBX|34|CE|57719-7^Conditions tested for in this NBS study^LN|1|LA12577-5 (IVA or 2MBG or GA-2 or EMA)|||A|||F|||20090714143552
OBX|35|CE|57719-7^Conditions tested for in this NBS study^LN|1|LA12513-0 (MSUD)|||A|||F|||20090714143552
OBX|36|CE|57719-7^Conditions tested for in this NBS study^LN|1|LA12538-7 (CH)|||A|||F|||20090714143552
OBX|37|CE|57719-7^Conditions tested for in this NBS study^LN|1|LA12528-8 (TYR-1)|||A|||F|||20090714143552

```

HL7 Message Critical Information: *Newborn Screening Test Results*

Below are some of the important segments that will be included in HL7 NBS electronic test result messages:

- **Message Header (MSH)** – Specifies details about the message (Message Type - Newborn Screening Results, Sender, HIE Receiver, etc.)

e.g. MSH|^~\&|SIS|NBS 850 MARINA BAY|||201103171117||ORU^R01|1234567890|T|2.5.1|||||||CALIFORNIA DEPARTMENT OF PUBLIC HEALTH

- **Patient Identifier (PID)** – Patient demographic information (Name, MRN, DOB, Sex, Ethnicity, etc.)

e.g. PID|1||924250^48011183^189-52-123/21-2010-72||Sunqlabrb^Amethyst||201103171117|Male||Other Race|||

- **Next of Kin (NK1)** – Next of Kin, providing information details of the mother (Name, Address, Number, etc.)

e.g. NK1|1|Bourne^Julia|Mother|427 4th Street^New York^NY ^94782|9163720117|||||||

- **Common Order (ORC)** – Transmits details common to all test results (Clinician, Hospital information on TRF Form Number, Hospital Order ID etc.)

e.g. ORC|RE|25989006^FormNumber||W12312312^HospOrderNum|||||||11356370^CUNNINGHAM^REBECCA^NPI|||

Observation Request (OBR) – Transmits information about an exam, diagnostic study/observation, or assessment that is specific to an order or result (Amino Acid, Acylcarnite, Cystic Fibrosis, Thyroid, Galactosemia, Hemoglobinopathis Panels, etc.)

e.g. OBR|1||9952580682|57717-1^Newborn screen card data panel ^LN|||20110525|||||||201105251200|FLT|

- **Observation Result (OBX)** – Carries the value of measured and computed results of the diagnostic observation (Birth weight and time, Acylcarnite newborn screen interpretation, Fatty acid oxidation defects, etc.)

e.g. OBX|1|NM|8339-4^Birthweight ^LN|1|3543|g |>2500|N|||F|||25052011|

HL7 Message Critical Information: *Acknowledgement / Error Message*

Below are some of the important segments that will be included in HL7 ACK/ NACK messages:

- **Message Header (MSH)** – Specifies details about the message (Message Type - Newborn Screening Results, Sender, HIE Receiver, etc.)

e.g. MSH|^~\&|SIS|NBS 850 MARINA BAY|||201103171117||ACK^R01^ACK|1234567890|T|2.5.1|||||||CALIFORNIA DEPARTMENT OF PUBLIC HEALTH

- **Message Acknowledgement (MSA)** – Includes HL7 message reference identifier and acknowledgement code, such as:

- Application Acknowledged (AA) - A positive code that indicates message that was accepted correctly
- Application Error (AE) – A negative code that indicates that were either a problem with the message structure, or the message itself
- Application Reject (AR) – A negative code that indicates that message was rejected

e.g. MSA|AA|1234567890

- **Error (ERR)*** – Provides detailed text on the exact error of the message

e.g. ERR||OBR^1|100^Segment sequence error^HL70357|E|||Missing required OBR segment|Email help desk for further

information on this error|||NET^Internet^helpdesk@hl7.org

**Note: Error Segment is only required if acknowledgement code is AE or AR*