

HIE TOOLS – USER GUIDE

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List of Revisions

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1	12/10/2013	Ankeet Mehta		Draft Version
2	02/18/2014	Ankeet Mehta		Changed for new screenshots
3	07/01/2016	Bhagyashree Mahadik		Changes done for modified test results added to screen, addition of ALD disorder, SCID confirmatory mailer, MSMS TPN addition.
4	09/13/2016	Bhagyashree Mahadik		Updated the document to add Receive Partial Result as Full.
5	1/19/2017	Deepa Nair		Updated to incorporate latest functionality available



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INTRODUCTION

Deloitte Consulting LLP, in collaboration with the Genetic Disease Screening Program (GDSP) of the California Department of Public Health (CDPH), developed and implemented the HIE tools to generate sample HL7 messages.

These tools will allow new partners to get quickly on boarded to Health Information Exchange (HIE). The HL7 Result Generator tool will allow user to generate various HL7 Result messages based on the user selection on the user interface. It will allow user to have various combination of disorders and then generate HL7 results.

The tool has the menu items as listed below:

- **HL7 Result Generator** – Generate sample NBS HL7 Result messages
- **HL7 Acknowledgement Validator** – Validate the HL7 acknowledgement (ACK) messages

Tool	URL
HL7 Result Generator	https://hiegateway.cdph.ca.gov/GDSPHL7Tools/HL7Message/HL7Generator
HL7 Acknowledgement Validator	https://hiegateway.cdph.ca.gov/GDSPHL7Tools/HL7Message/HL7ACKNACKValidator

1.0 NBS HL7 RESULT GENERATOR

NBS HL7 Result Generator is a tool to generate sample HL7 messages which resemble the actual NBS results sent through Health Information Exchange (HIE) interface.

HL7 Result Generator tool allows user to generate a variety of NBS HL7 results. Results are generated based on the interpretation selected for each disorder in the tool interface.

➤ **STEPS TO GENERATE HL7 RESULT**

1. Click on the HL7 Result Generator menu item to open the tool.

The screenshot below shows the user interface of HIE Tools – HL7 Generator.

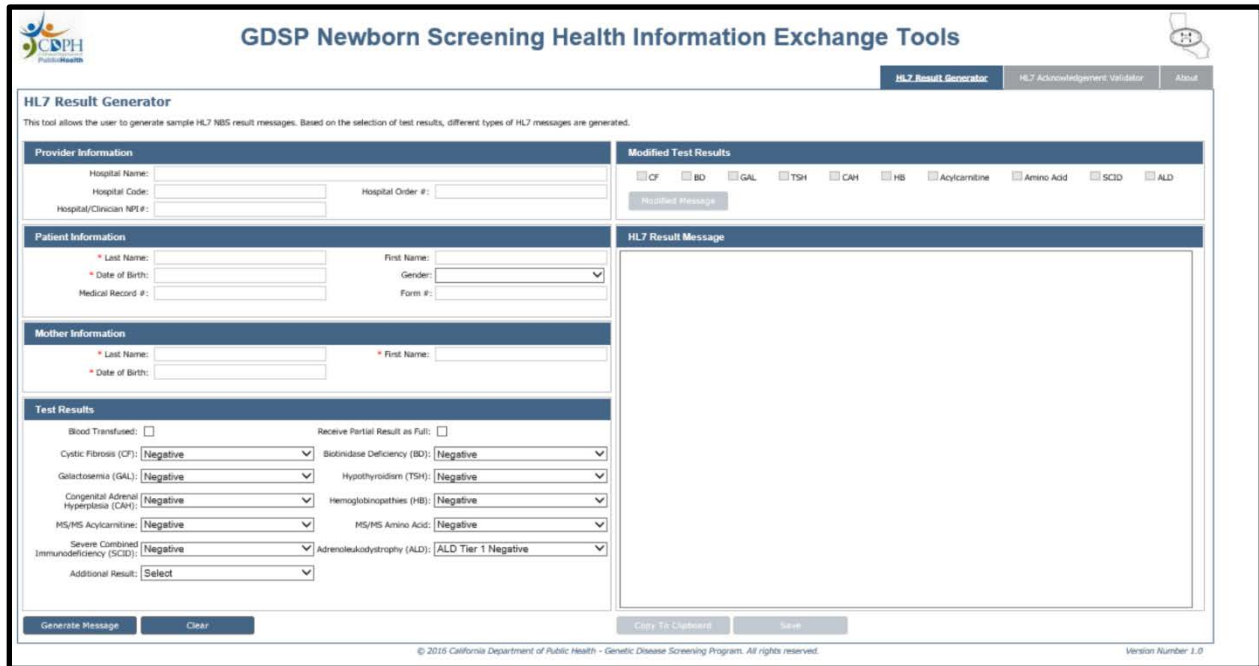


Figure 1

2. The fields marked with asterisk (*) are mandatory fields which include:

- Patient Last Name
- Patient Date of Birth
- Mother Last Name
- Mother First Name
- Mother Date of Birth



Enter the data in the input fields as shown in screenshot below.

HL7 Result Generator

This tool allows the user to generate sample HL7 NBS result messages. Based on the selection of test results, different types of HL7 messages are generated.

Provider Information

Hospital Name: Stanford Hospital & Clinic
 Hospital Code: H001 Hospital Order #:
 Hospital/Clinician NPI #:

Modified Test Results

CF BD GAL TSH CAH HB Acycarnine Amino Acid SCID ALD

Modified Message

HL7 Result Message

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Figure 2

- Click on the 'Generate Message' button. HL7 Message will be displayed in the HL7 Result Message textbox. Below is the screenshot of generated HL7 message.

HL7 Result Generator

This tool allows the user to generate sample HL7 NBS result messages. Based on the selection of test results, different types of HL7 messages are generated.

Provider Information

Hospital Name: Stanford Hospital & Clinic
 Hospital Code: H001 Hospital Order #:
 Hospital/Clinician NPI #:

Modified Test Results

CF BD GAL TSH CAH HB Acycarnine Amino Acid SCID ALD

Modified Message

HL7 Result Message

```
MSH|^~\&|S120009|S120009|S120009|S120009|1222344^L.M.N|^L.M.N|2016091202425||OBX^R01^OBD^1
PID|||^^4892^MR||Ramirez^John^^^S||2014020400001||2106-0^White|||||12126-0^Sex^M|^
N11|Ramirez^Maria^MTH^Mother|850 Maxine Bay Parkway, 8 APT100A^Richmond^CA^94806-4000^DU
ORC|RE|^FormNumber||^ HospOrdNumber|||||^^KIM^JULIAN^*****NP2|||||Stanford Hospital
OBR|1|^FormNumber||84029-0^NB^Newborn Panel Patient^ANIC^|||||120140204000000|||||KIM^J
OBR|2|^FormNumber||57120-1^Newborn Screening Report summary panel^|||||20140204000000|||||
ORC|1|CE|57121-0^Reason for lab test in Dried blood spot^LN^|||||LA12421-0^S^Initial screen^
OBR|2|CE|57120-9^Sample quality of Dried blood spot^LN^|||||LA12422-0^S^Acceptable^LN^|||H
OBR|3|CE|57130-7^Newborn screening report - overall interpretation^LN^|||||LA12440-0^S^Done
OBR|4|CE|57131-0^Newborn conditions with positive markers [Identifier] in Dried blood spot^
OBR|5|CE|57120-5^Newborn conditions with equivocal markers [Identifier] in Dried blood spot^
OBR|6|TX|57124-7^Newborn screening short narrative summary^LN^|||||Testing Lab - WESTERN CL
OBR|7|TX|57129-9^Full newborn screening summary report for display or printing^LN^|||||11111H
OBR|8|CE|57119-7^Conditions tested for in this newborn screening study [Identifier] in Drie
OBR|9|CE|57119-7^Conditions tested for in this newborn screening study [Identifier] in Drie
OBR|10|CE|57119-7^Conditions tested for in this newborn screening study [Identifier] in Drie
OBR|11|CE|57119-7^Conditions tested for in this newborn screening study [Identifier] in Drie
OBR|12|CE|57119-7^Conditions tested for in this newborn screening study [Identifier] in Drie
OBR|13|CE|57119-7^Conditions tested for in this newborn screening study [Identifier] in Drie
OBR|14|CE|57119-7^Conditions tested for in this newborn screening study [Identifier] in Drie
OBR|15|CE|57119-7^Conditions tested for in this newborn screening study [Identifier] in Drie
OBR|16|CE|57119-7^Conditions tested for in this newborn screening study [Identifier] in Drie
OBR|17|CE|57119-7^Conditions tested for in this newborn screening study [Identifier] in Drie
OBR|18|CE|57119-7^Conditions tested for in this newborn screening study [Identifier] in Drie
OBR|19|CE|57119-7^Conditions tested for in this newborn screening study [Identifier] in Drie
OBR|20|CE|57119-7^Conditions tested for in this newborn screening study [Identifier] in Drie
OBR|21|CE|57119-7^Conditions tested for in this newborn screening study [Identifier] in Drie
OBR|22|CE|57119-7^Conditions tested for in this newborn screening study [Identifier] in Drie
OBR|23|CE|57119-7^Conditions tested for in this newborn screening study [Identifier] in Drie
```

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Figure 3

4. User can “Copy and Save Results” by using any of the below listed options
 - User can copy the generated HL7 message to clipboard by clicking on ‘Copy To Clipboard’ button. This feature is available only in Internet Explorer web browser.
 - User can save the generated HL7 message by clicking on the ‘Save’ button. The result message is saved to a file in .hl7 format with default filename as *SampleHL7Result*.
5. User can clear the form data (input fields and HL7 Result Message) by clicking the ‘Clear’ button. A popup appears for user confirmation to clear form data. Click on ‘Yes’ button to clear the form.

Figure 4

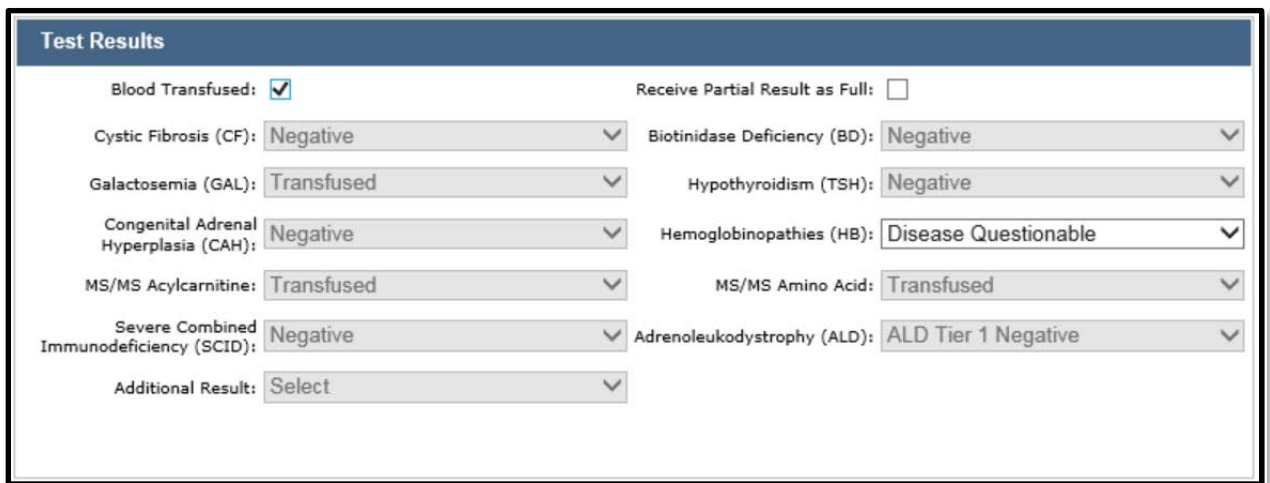
➤ **ADDITIONAL FUNCTIONALITIES**

User can also make different combinations in the Test Results and the HL7 result message will be generated accordingly. Following are some of the scenarios for which HL7 message can be generated:

1. Blood Transfused (CheckBox):

In case of scenarios where baby blood is transfused then select the option by clicking the ‘Blood Transfused’ check box. When user selects this option

- MS/MS and Galactosemia will default to ‘Transfused’
- For Hemoglobinopathies the below options will be available.
 - a. Disease Questionable
 - b. HB Uninterpretable
 - c. HB Variant



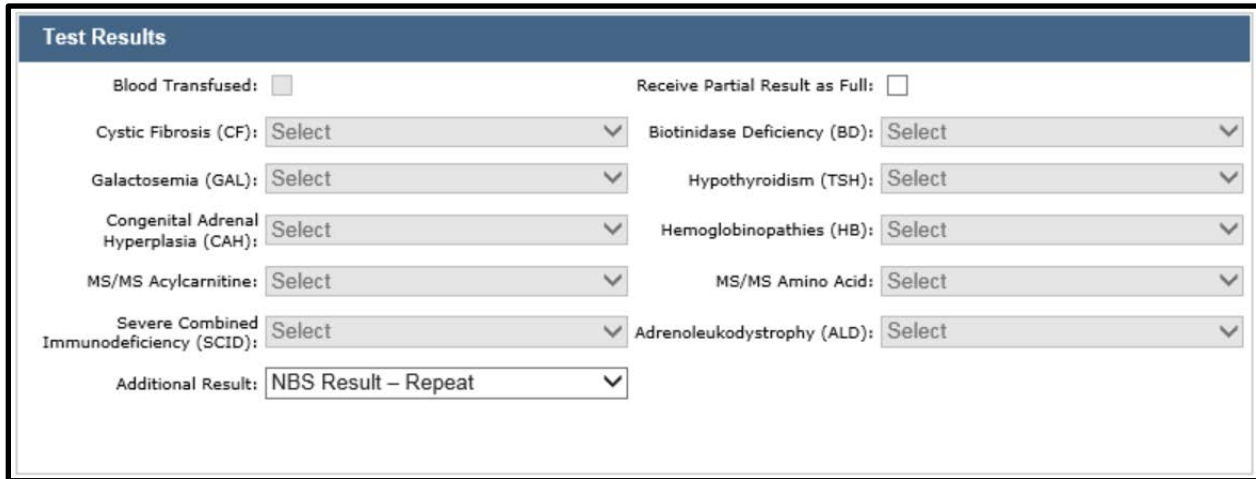
The screenshot shows a 'Test Results' form with the following fields:

- Blood Transfused:**
- Receive Partial Result as Full:**
- Cystic Fibrosis (CF):** Negative
- Biotinidase Deficiency (BD):** Negative
- Galactosemia (GAL):** Transfused
- Hypothyroidism (TSH):** Negative
- Congenital Adrenal Hyperplasia (CAH):** Negative
- Hemoglobinopathies (HB):** Disease Questionable
- MS/MS Acylcarnitine:** Transfused
- MS/MS Amino Acid:** Transfused
- Severe Combined Immunodeficiency (SCID):** Negative
- Adrenoleukodystrophy (ALD):** ALD Tier 1 Negative
- Additional Result:** Select

Figure 5

- 2. Additional Results (Dropdown):** Additional Result types are different from the NBS HL7 results generated for a normal or specific positive case. Structurally the message will be more or less similar but may vary from case to case basis.

When any of the Additional Result values is selected, all other fields in Test Results section are disabled shown below.



The screenshot shows a form titled "Test Results" with the following fields:

- Blood Transfused:
- Receive Partial Result as Full:
- Cystic Fibrosis (CF): Select
- Biotinidase Deficiency (BD): Select
- Galactosemia (GAL): Select
- Hypothyroidism (TSH): Select
- Congenital Adrenal Hyperplasia (CAH): Select
- Hemoglobinopathies (HB): Select
- MS/MS Acylcarnitine: Select
- MS/MS Amino Acid: Select
- Severe Combined Immunodeficiency (SCID): Select
- Adrenoleukodystrophy (ALD): Select
- Additional Result: NBS Result – Repeat

Figure 6

Listed below are the Additional Results that can be generated:

i. NBS Result – Initial (Inadequate Specimen)

- This type of result is generated when the initial specimen collected from a patient was inadequate for testing and deriving interpretations.
- Newborn Screening Report summary panel in HL7 result message will have *Reason for lab test in Dried blood spot* (OBX with LOINC 57721-3) with reason (Observation Value - OBX.5). as “Subsequent screen - for clarification of initial results (not by law or protocol)”.
- Newborn Screening Report summary panel in HL7 result message will have *Sample quality of Dried blood spot* (OBX with LOINC 57718-9) with Observation Value (OBX.5) as “Specimen quantity insufficient for testing”.
- Narrative Summary in HL7 result message will have –
 - Action Identifier as ACTION REQUIRED and
 - Follow-up message as “*** This specimen was inadequate for testing for the following reason”
- Other disorder panels will not be present

ii. NBS Result – Initial (Too Early or Missing Information)

- This type of result is generated if the specimen collection time was within 12 hours of baby's birth.
- Every OBR segment in HL7 result message must have Specimen Collection date (OBR.7) less than 12 hours from baby birth (PID.7).
- Narrative Summary in HL7 result message will have -
 - Action Identifier as ACTION REQUIRED and
 - Follow-up message
- Other disorder panels will be present

iii. NBS Result – Repeat

- This type of result is generated when second specimen is collected since the first specimen collected was inadequate for testing. This result, syntactically is similar to the initial result case
- This result is sent in addition to a previous *NBS HL7 Result – Initial (Inadequate Specimen)* or *NBS Result – Initial (Too Early or Missing Information)*
- Newborn Screening Report summary panel in HL7 result message will have Reason for lab test in Dried blood spot (OBX with LOINC 57721-3) with reason (Observation Value - OBX.5) as “Subsequent screen - for clarification of initial results (not by law or protocol)”
- Newborn Screening Report summary panel in HL7 result message will have Sample quality of Dried blood spot (OBX with LOINC 57718-9) with Observation Value (OBX.5) as “Acceptable”
- Other disorder panels will be present

iv. NBS Result – Repeat (SCID Test)

- This type of result is generated when second specimen is collected to specifically re-test for SCID disorder.
- This result is sent in addition to an Initial NBS Result sent earlier.
- The result will have Newborn Screening Report summary panel with Reason for lab test in Dried blood spot as “Subsequent screen - for clarification of initial results (not by law or protocol”.
- Disorder panel present only for the SCID disorder

v. NBS Result – CFTR DNA Sequencing

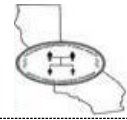
- This type of result is generated when specimen collected is found to be positive for Cystic Fibrosis disorder.
- This result is sent in addition to an Initial NBS Result sent before.
- Apart from the complete result message, additional CF specific result will be sent.
- Narrative Summary in HL7 result message will have
 - Action Identifier as ACTION REQUIRED and
 - Follow-up message.
- Disorder panel present only for the Cystic Fibrosis disorder.

vi. NBS Result – SCID Confirmatory

- This type of result is generated when specimen collected is found to be SCID positive or confirmatory test is requested for SCID disorder.
- This result is sent in addition to Initial NBS Result sent before.
- Apart from the complete result message, additional SCID specific result will be sent.
- Narrative Summary in HL7 result message will have
 - Action Identifier as ACTION REQUIRED and
 - Follow-up message.
- Disorder panel present only for the SCID disorder.
- Hospital Order Number added on screen is not included in this mailer.

vii. NBS Result – ALD Sequencing with Mutation

- This type of result is generated when specimen collected is found to be ALD positive with mutation.
- This result is sent in addition to NBS Result sent before.
- ALD sequencing result mailer is sent as an additional result mailer as a correction to NBS result mailer on arrival of ALD sequencing results.
- Narrative Summary in HL7 result message will have
 - Action Identifier as ACTION REQUIRED and
 - Follow-up message.



viii. NBS Result – ALD Sequencing without Mutation

- This type of result is generated when specimen collected is found to be ALD positive without mutation.
- This result is sent in addition to NBS Result sent before.
- ALD sequencing result mailer is sent as an additional result mailer as a correction to NBS result mailer on arrival of ALD sequencing results.
- Narrative Summary in HL7 result message will have
 - Action Identifier as ACTION REQUIRED and
 - Follow-up message.

3. Modified Message (Button):

Modified mailers are modifications sent after the initial mailer was already sent. The modified content will be denoted by Corrected Flag – “C”. There is an option for user to generate a modified HL7 test results for any disorder.

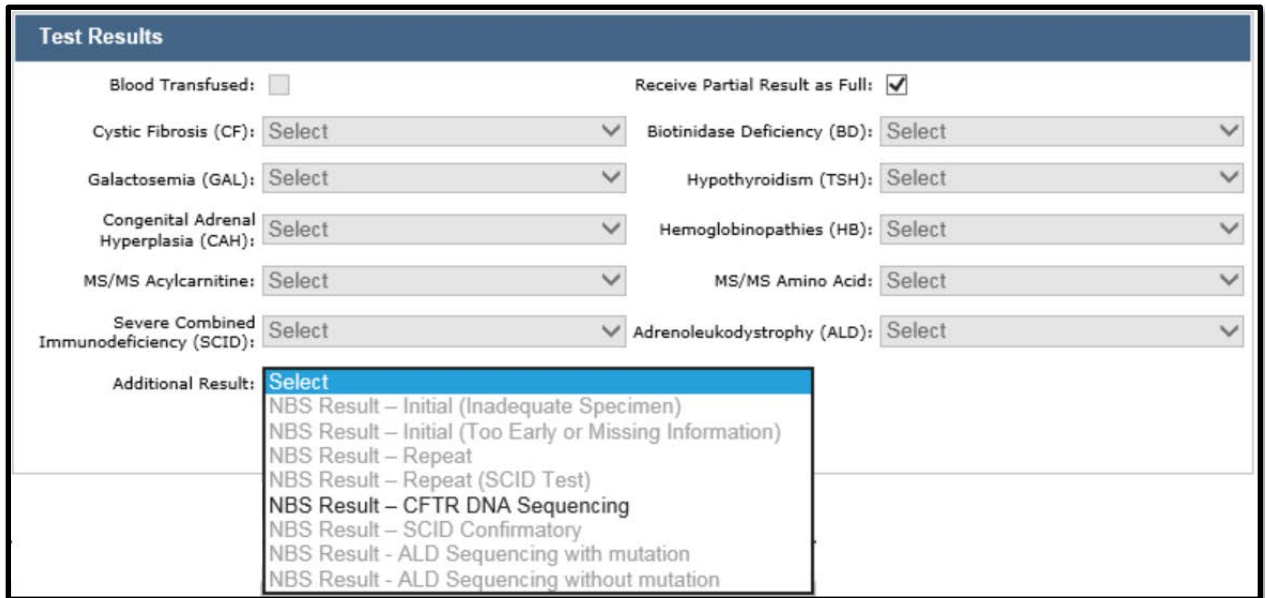
- The Modified Message button is enabled only if result mailer is first generated by clicking generate message.
- User can select disorder check box option and click Modified Message button to generate modified HL7 result in the HL7 Result Message panel.
- The generated HL7 message will have text ‘Modified’ in the narrative summary.
- And the disorders selected for modification are marked as Corrected (‘C’) in OBX segments to denote that the segment has been modified. Also the corresponding OBR is marked as corrected.
- For Additional Test Results the modified message option is not available.

Figure 7

4. Receive Partial Result as Full (Checkbox):

Mailers like CF Sequencing are Partial mailers as it consists of details related to CF panel alone whereas the NBS Results are Full Mailers which are sent with all disorders. Hence an option to receive Partial mailers as Full mailers are available whereby the partial mailer contents will be merged with the initial full mailer sent.

- User can select Receive Partial Result as Full checkbox to generate partial result as full.
- Currently only CF Sequencing result mailer qualifies to be generated as full mailer



The screenshot shows a form titled "Test Results" with the following fields:

- Blood Transfused:
- Receive Partial Result as Full:
- Cystic Fibrosis (CF):
- Biotinidase Deficiency (BD):
- Galactosemia (GAL):
- Hypothyroidism (TSH):
- Congenital Adrenal Hyperplasia (CAH):
- Hemoglobinopathies (HB):
- MS/MS Acylcarnitine:
- MS/MS Amino Acid:
- Severe Combined Immunodeficiency (SCID):
- Adrenoleukodystrophy (ALD):
- Additional Result:
 - NBS Result – Initial (Inadequate Specimen)
 - NBS Result – Initial (Too Early or Missing Information)
 - NBS Result – Repeat
 - NBS Result – Repeat (SCID Test)
 - NBS Result – CFTR DNA Sequencing
 - NBS Result – SCID Confirmatory
 - NBS Result - ALD Sequencing with mutation
 - NBS Result - ALD Sequencing without mutation

Figure 8

2.0 HL7 ACKNOWLEDGEMENT VALIDATOR

When GDSP sends NBS HL7 Result message to health care provider, it expects to receive an acknowledgement (ACK/NACK) message to confirm successful transmission and processing. GDSP supports the 'Original acknowledgment mode' protocol for message acknowledgement.

HL7 Acknowledgement Validator is a tool to validate HL7 acknowledgements (HL7 2.5.1 format). Refer specifications described in the section 4.0 of *4A_HIE NBS Data Exchange Specification.docx* document from onboarding packet.

➤ STEPS TO VALIDATE ACKNOWLEDGEMENT MESSAGES

HL7 Acknowledgement Validator tool can be used to validate HL7 Acknowledgement messages using the following steps:

1. Navigate to HL7 Acknowledgement Validator tool.

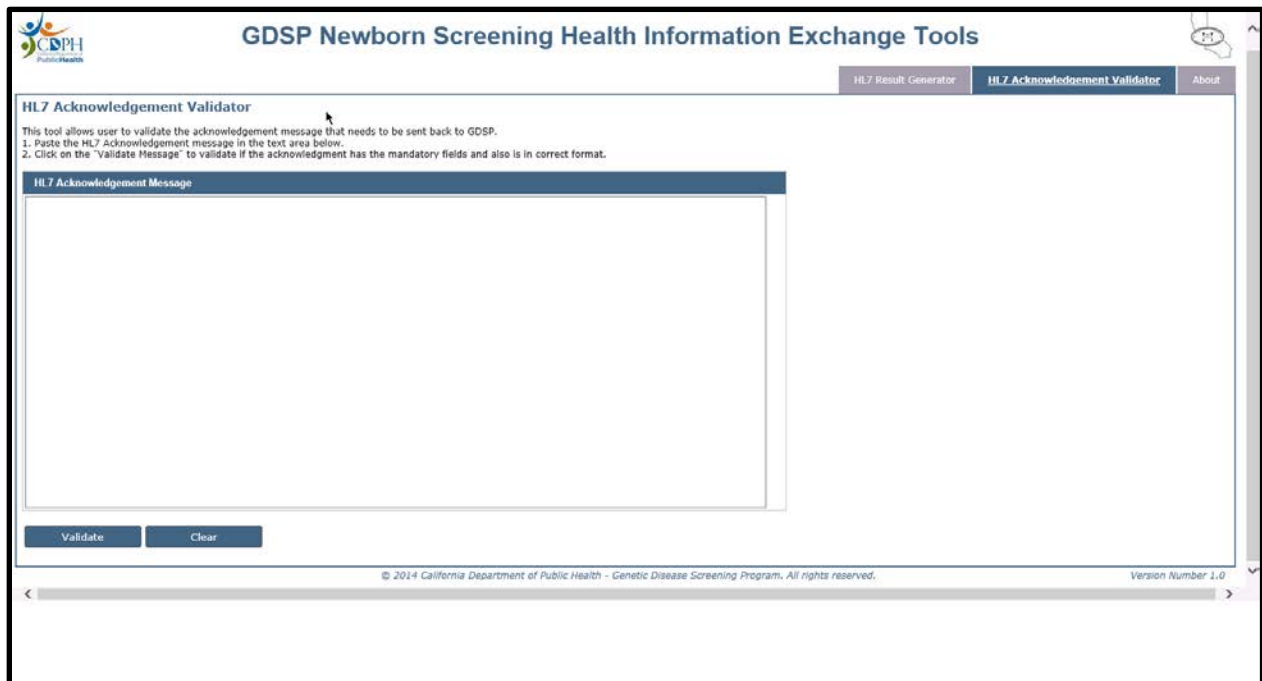


Figure 9

2. Paste the acknowledgement in the HL7 Acknowledgement Message text area. Refer to the sample acknowledgement messages in the onboarding packet.
3. Click on the Validate button at the bottom of the page. This brings up the validation result message on top of the HL7 Acknowledgement Message panel as shown below.

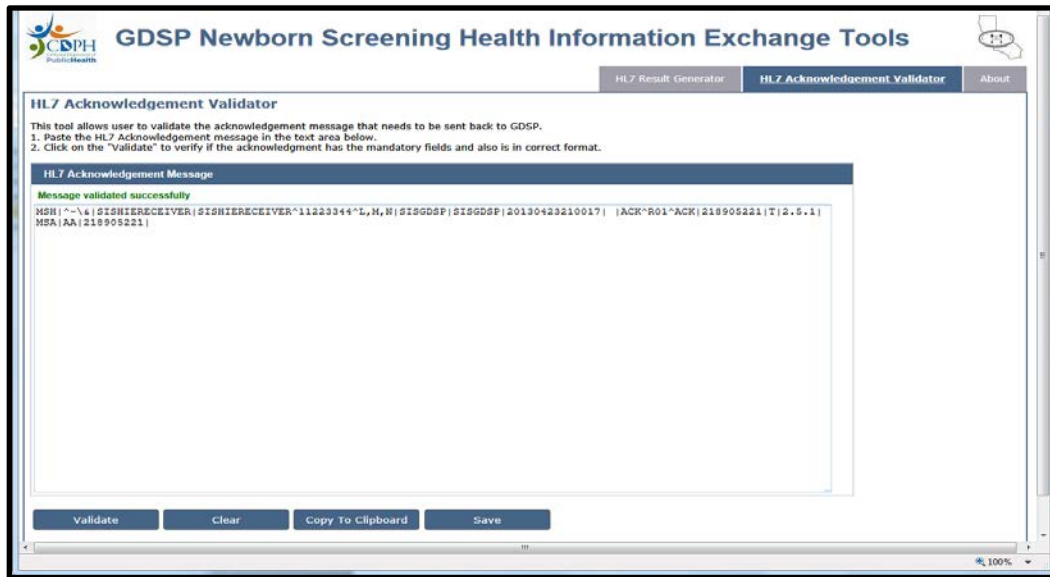


Figure 10

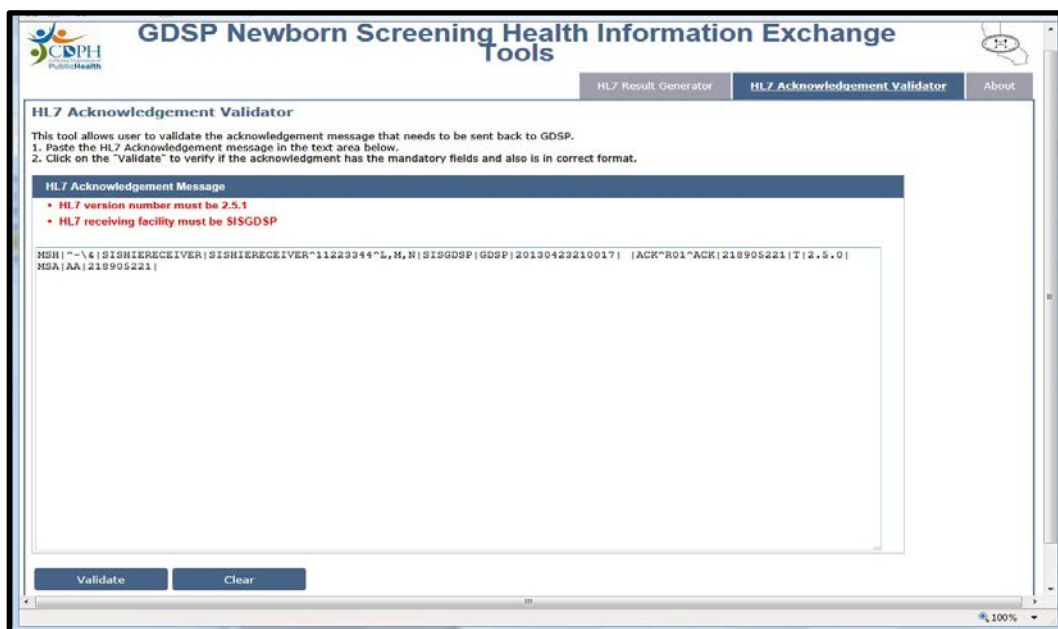
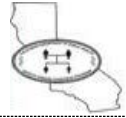


Figure 11



4. Copy and Save Acknowledgement

1. User can copy the generated HL7 message to clipboard by clicking on 'Copy To Clipboard' button. This feature is available only in Internet Explorer web browser.
2. User can save the validated acknowledgement by clicking the 'Save' button. The acknowledgement message is saved to a file in .hl7 format with default filename as *SampleHL7Ack*.
5. User can clear the acknowledgement message by clicking the 'Clear' button. A popup appears for user confirmation to clear form data. Click 'Yes' button to clear the form.