

# Xpert<sup>®</sup> NPM1 Mutation Laboratory Information System Guidance

## **REF** GXNPM1-CE-10

ADF: **Xpert NPM1 Mutation**

**Version 1**

**Purpose:** To provide information for enabling a Laboratory Information System (LIS) interface for the Xpert<sup>®</sup> NPM1 Mutation test on GeneXpert<sup>®</sup> Systems.

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If you need further assistance, please contact Cepheid Technical Support at <https://www.cepheid.com/en/about/contact-us> or email [techsupport@cepheid.com](mailto:techsupport@cepheid.com).

## 1 Host Communication in GeneXpert® System

### 1.1 Consult your LIS System Administrator:

Consult with your LIS System Administrator when interfacing the new assay to LIS.

### 1.2 Enable Host Communication:

If the GeneXpert system is not already configured for LIS host communication, follow the instructions in your GeneXpert System's User Guide: "Configuring Host Communications for a LIS."

### 1.3 Assay Host Test Code and Result Code Configuration:

Assay Host Test Code and Result Code must be defined in the GeneXpert system.

Test codes can be user-defined. Cepheid provided the recommended test code in section 1.4. Consider your organization's need to use a different test code as need.

### 1.4 Suggested Assay Host Test Codes

| ADF Name / Assay Name | ADF Version | Assay Host Test Code | Analyte Name | Result Code       | Possible Result Values                                    |
|-----------------------|-------------|----------------------|--------------|-------------------|---|
| Xpress NPM1 Mutation  | 1           | <sup>1</sup> NPM1    | NPM1         | <sup>2</sup> N.A. | DETECTED<br>NOT DETECTED<br>INVALID<br>ERROR<br>NO RESULT |

<sup>1</sup>**Note:** As a Single-Result Assay, the Assay Host Test Code is used as the Upload and Download Code.

<sup>2</sup>**Note:** Result Code is not applicable for Single-Result Assay

## 2 Example Messages

These example messages can be used by an LIS interface analyst to understand the structure and content of Xpert NPM1 Mutation test results.

### 2.1 Example Result Messages

#### 2.1.1 Example ASTM Messages

##### Example ASTM Message: NPM1 Mutation DETECTED

```
H|@^\|GXM-83710273313||GeneXpert PC^GeneXpert^6.4||||LIS||P|1394-97|20220722|132154
P|1||||^^^|
O|1|220331_Pos||^NPM1|R|20220331104522||||ORH||||F
R|1|^NPM1^Xpert NPM1 Mutation^1^^|DETECTED [0.082%]^0.082%|0.030 to 500.0||F||Jane Doe|20220331104522|20220331130540|ComputerName
^702399^749311^560281398^01099^20901224|
R|2|^NPM1^^NPM1 Mutation^|POS^|||
R|3|^NPM1^^NPM1 Mutation^Ct|^26.3|||
R|4|^NPM1^^NPM1 Mutation^EndPt|^246.0|||
R|5|^NPM1^^NPM1 Mutation^Delta Ct|^-11.7|||
R|6|^NPM1^^ABL^|PASS^|||
R|7|^NPM1^^ABL^Ct|^14.6|||
R|8|^NPM1^^ABL^EndPt|^229.0|||
L|1|N
```

##### Example ASTM Message: NPM1 Mutation NOT DETECTED

```
H|@^\|GXM-85121438604||GeneXpert PC^GeneXpert^6.4||||LIS||P|1394-97|20220722|132155
P|1||||^^^|
O|1|220331_Neg||^NPM1|R|20220331104511||||ORH||||F
R|1|^NPM1^Xpert NPM1 Mutation^1^^|NOT DETECTED [Sufficient ABL transcript]^|^0.030 to 500.0||F||Jane
Doe|20220331104511|20220331130516|ComputerName ^702399^734110^560281399^01099^20901224|
R|2|^NPM1^^NPM1 Mutation^|NEG^|||
R|3|^NPM1^^NPM1 Mutation^Ct|^0.0|||
R|4|^NPM1^^NPM1 Mutation^EndPt|^0.0|||
R|5|^NPM1^^NPM1 Mutation^Delta Ct|^|||
R|6|^NPM1^^ABL^|PASS^|||
```

```
R|7|^^^NPM1^^^ABL^Ct|^15.1|||
R|8|^^^NPM1^^^ABL^EndPt|^225.0|||
L|1|N
```

**Example ASTM Message: ERROR**

```
H|@^\|GXM-35077465372||GeneXpert PC^GeneXpert^6.4||||LIS||P|1394-97|20220722|132150
P|1||||^^^|||||||||||||||||||||||||
O|1|220331_Error||^NPM1|R|20220331104549||||||ORH|||||||F
R|1|^NPM1^Xpert NPM1 Mutation^1^^|ERROR^|%|0.030 to 500.0|||F||Jane Doe|20220331104549|20220331115747|ComputerName
^702399^804479^560281401^01099^20901224|
C|1||Error^5017^Post-run analysis error^Error 5017: [QC2] probe check failed. Probe check value of 0 for reading number 2 was below the valid level of
5^20220331115748|N
C|2||Error^5017^Post-run analysis error^Error 5017: [QC1] probe check failed. Probe check value of 0 for reading number 2 was below the valid level of
5^20220331115748|N
R|2|^NPM1^^^NPM1 Mutation^|NO RESULT^|||
R|3|^NPM1^^^NPM1 Mutation^Ct|^0.0|||
R|4|^NPM1^^^NPM1 Mutation^EndPt|^0.0|||
R|5|^NPM1^^^NPM1 Mutation^Delta Ct|^|||
R|6|^NPM1^^^ABL^|NO RESULT^|||
R|7|^NPM1^^^ABL^Ct|^0.0|||
R|8|^NPM1^^^ABL^EndPt|^0.0|||
L|1|N
```

**Example ASTM Message: INVALID**

```
H|@^\|GXM-56146363140||GeneXpert PC^GeneXpert^6.4||||LIS||P|1394-97|20220722|132152
P|1||||^^^|||||||||||||||||||||||||
O|1|220331_Invalid||^NPM1|R|20220331104536||||||ORH|||||||F
R|1|^NPM1^Xpert NPM1 Mutation^1^^|INVALID [No ABL transcript]^|%|0.030 to 500.0|||F||Jane
Doe|20220331104536|20220331130532|ComputerName ^702399^667275^560281400^01099^20901224|
R|2|^NPM1^^^NPM1 Mutation^|INVALID^|||
R|3|^NPM1^^^NPM1 Mutation^Ct|^0.0|||
R|4|^NPM1^^^NPM1 Mutation^EndPt|^1.0|||
R|5|^NPM1^^^NPM1 Mutation^Delta Ct|^|||
R|6|^NPM1^^^ABL^|FAIL^|||
```

```
R|7|^^^NPM1^^^ABL^Ct|^0.0||  
R|8|^^^NPM1^^^ABL^EndPt|^0.0||  
L|1|N
```

**Example ASTM Message: NO RESULT**

<DATA NOT AVAILABLE>

## 2.1.2 Example ASTM Download Messages

**Successful order download.**

**Query message**

```
H|@^|\GXM-63607472380||GeneXpert PC^GeneXpert^6.3||||LIS||P|1394-97|20230125094215  
Q|1|^TESTSID^^|^^|O@N  
L|1|N
```

**Order download message**

```
H|@^|\36bcf402-b4c5-4fc2-932d-ae63c4e2cb37||LIS^^||||GeneXpert||P|1394-97|  
P|1||||^^^  
O|1|TESTSID||^^^NPM1|R|20230125094151||||||ORH||^|  
L|1|N
```

**Order cancelled**

```
H|@^|\GXM-86654266654||GeneXpert PC^GeneXpert^6.3||||LIS||P|1394-97|20220621154707  
P|1||||^^^|  
O|1|SID1|CepheidVM-PC-LT57GEGSBA-07|^NPM1|20220621154242||||C|||ORH|||X  
L|1|N
```

## 2.1.3 Example HL7 Download Messages

**Successful Order download.**

**Query Message**

```
MSH|^~\&|GeneXpert PC^GeneXpert^6.3||LIS||20230125094920||QBP^Z03^QBP_Z03|GXM-34401616371|P|2.5|
```

QPD|Z03^HOST QUERY|GXM-34401616371||TESTSID||  
RCP|

**Order download message**

MSH|^~\&|LIS^^|GeneXpert||||0a984080-b59b-49f2-9a2b-a6180e6e3378|P|2.5  
PID|1||||^^^  
ORC|RE|1|||||20230125094904  
OBR|1||NPM1||||||||||||||  
TQ1||||||R  
SPM|1|TESTSID^||ORH|||||P

**Order cancelled**

H|@^\GXM-70453463486||GeneXpert PC^GeneXpert^6.3||||LIS||P|1394-97|20220621160453  
P|1||||^^^||||||||||||||  
O|1|SID2|CepheidVM-PC-XLREJEGSBA-08|^^^NMP1|R|20220621160347||||C||||ORH|||||||X  
L|1|N

## 2.1.4 Example HL7 Messages

### Example HL7 Message: NPM1 Mutation DETECTED

```
MSH|^~\&|GeneXpert PC^GeneXpert^6.4||LIS||20220722143543||ORU^R32^ORU_R30|GXM-51263042376|P|2.5|||||||
PID|1||||^|20220331104522
ORC|RE|1|||||20220331104522
OBR|1||NPM1|||||F
TQ1|||||20220331104522|20220331130540|R
OBX|1|ST|&NPM1&Xpert NPM1 Mutation&1|&|DETECTED [0.082%]^0.082|%|0.030-500.0||||F||||^Jane
Doe||20901224~01099~560281398~749311~702399~ComputerName
OBX|2|ST|&NPM1&&|NPM1 Mutation&|POS^|
OBX|3|ST|&NPM1&&|NPM1 Mutation&Ct|^26.3|
OBX|4|ST|&NPM1&&|NPM1 Mutation&EndPt|^246.0|
OBX|5|ST|&NPM1&&|NPM1 Mutation&Delta Ct|^-11.7|
OBX|6|ST|&NPM1&&|ABL&|PASS^|
OBX|7|ST|&NPM1&&|ABL&Ct|^14.6|
OBX|8|ST|&NPM1&&|ABL&EndPt|^229.0|
SPM|1|220331_Pos^|ORH|||||P
```

### Example HL7 Message: NPM1 Mutation NOT DETECTED

```
MSH|^~\&|GeneXpert PC^GeneXpert^6.4||LIS||20220722143545||ORU^R32^ORU_R30|GXM-52304285822|P|2.5|||||||
PID|1||||^|20220331104511
ORC|RE|1|||||20220331104511
OBR|1||NPM1|||||F
TQ1|||||20220331104511|20220331130516|R
OBX|1|ST|&NPM1&Xpert NPM1 Mutation&1|&|NOT DETECTED [Sufficient ABL transcript]^|^%|0.030-500.0||||F||||^Jane
Doe||20901224~01099~560281399~734110~702399~ ComputerName
OBX|2|ST|&NPM1&&|NPM1 Mutation&|NEG^|
OBX|3|ST|&NPM1&&|NPM1 Mutation&Ct|^0.0|
OBX|4|ST|&NPM1&&|NPM1 Mutation&EndPt|^0.0|
OBX|5|ST|&NPM1&&|NPM1 Mutation&Delta Ct|^|
OBX|6|ST|&NPM1&&|ABL&|PASS^|
OBX|7|ST|&NPM1&&|ABL&Ct|^15.1|
OBX|8|ST|&NPM1&&|ABL&EndPt|^225.0|
```

SPM|1|220331\_Neg^||ORH|||||P



**Example HL7 Message: ERROR**

```
MSH|^~&|GeneXpert PC^GeneXpert^6.4||LIS||20220722143537||ORU^R32^ORU_R30|GXM-45611443271|P|2.5|||||||
PID|1|||^^^|^^^|
ORC|RE|1|||20220331104549
OBR|1||NPM1|F
TQ1|||20220331104549|20220331115747|R
OBX|1|ST|&NPM1&Xpert NPM1 Mutation&1|&|ERROR^|%|0.030-500.0|||F|||Jane
Doe||20901224~01099~560281401~804479~702399~ComputerName
NTE|1|L|Error^5017^Post-run analysis error^Error 5017: [QC2] probe check failed. Probe check value of 0 for reading number 2 was below the valid level
of 5^20220331115748
NTE|2|L|Error^5017^Post-run analysis error^Error 5017: [QC1] probe check failed. Probe check value of 0 for reading number 2 was below the valid level
of 5^20220331115748
OBX|2|ST|&NPM1&&|NPM1 Mutation&|NO RESULT^||
OBX|3|ST|&NPM1&&|NPM1 Mutation&Ct|^0.0||
OBX|4|ST|&NPM1&&|NPM1 Mutation&EndPt|^0.0||
OBX|5|ST|&NPM1&&|NPM1 Mutation&Delta Ct|^||
OBX|6|ST|&NPM1&&|ABL&|NO RESULT^||
OBX|7|ST|&NPM1&&|ABL&Ct|^0.0||
OBX|8|ST|&NPM1&&|ABL&EndPt|^0.0||
SPM|1|220331_Error^||ORH|||P
```

**Example HL7 Message: INVALID**

```
MSH|^~&|GeneXpert PC^GeneXpert^6.4||LIS||20220722143540||ORU^R32^ORU_R30|GXM-78038602564|P|2.5|||||||
PID|1|||^^^|^^^|
ORC|RE|1|||20220331104536
OBR|1||NPM1|F
TQ1|||20220331104536|20220331130532|R
OBX|1|ST|&NPM1&Xpert NPM1 Mutation&1|&|INVALID [No ABL transcript]^|%|0.030-500.0|||F|||Jane
Doe||20901224~01099~560281400~667275~702399~ComputerName
OBX|2|ST|&NPM1&&|NPM1 Mutation&|INVALID^||
OBX|3|ST|&NPM1&&|NPM1 Mutation&Ct|^0.0||
OBX|4|ST|&NPM1&&|NPM1 Mutation&EndPt|^1.0||
OBX|5|ST|&NPM1&&|NPM1 Mutation&Delta Ct|^||
OBX|6|ST|&NPM1&&|ABL&|FAIL^||
```

```
OBX|7|ST|&NPM1&&|ABL&Ct|^0.0||  
OBX|8|ST|&NPM1&&|ABL&EndPt|^0.0||  
SPM|1|220331_Invalid^||ORH|||||P
```

**Example HL7 Message: NO RESULT**

<DATA NOT AVAILABLE>

### 3 Observation Language Translations Table

The table below provides a consolidated translation of the analyte value strings for all the languages supported by the GeneXpert System.

| # | Language   | DETECTED  | NOT DETECTED    | ERROR     | INVALID          | NO RESULT        |
|---|------------|-----------|-----------------|-----------|------------------|------------------|
| 1 | English    | DETECTED  | NOT DETECTED    | ERROR     | INVALID          | NO RESULT        |
| 2 | French     | DÉTECTÉ   | NON DÉTECTÉ     | ERREUR    | NON VALIDE       | PAS DE RÉSULTAT  |
| 3 | German     | ERMITTELT | NICHT ERMITTELT | FEHLER    | UNGÜLTIG         | KEIN ERGEBNIS    |
| 4 | Spanish    | DETECTADO | NO DETECTADO    | INCERTO   | INDETERMINADA    | SIN RESULTADO    |
| 5 | Italian    | RILEVATO  | NON RILEVATO    | ERRORE    | NON VALIDO       | NESSUN RISULTATO |
| 6 | Portuguese | DETETADO  | NÃO DETETADO    | ERRO      | INVÁLIDO         | SEM RESULTADO    |
| 7 | Russian    | ОБНАРУЖЕН | НЕ ОБНАРУЖЕН    | ОШИБКА    | НЕДЕЙСТВИТЕЛЬНЫЙ | НЕТ РЕЗУЛЬТАТА   |
| 8 | Ukrainian  | ВІЯВЛЕНО  | НЕ ВІЯВЛЕНО     | НЕДІЙСНИЙ | НЕДІЙСНИЙ        | НЕМАЄ РЕЗУЛЬТАТУ |
| 9 | Japanese   | DETECTED  | NOT DETECTED    | ERROR     | INVALID          | NO RESULT        |