**Cerner Optum ORU Lab Requirements**

**Version 1.3**

**Prepared By: Art Schwartz & Dan Olszewski**

**Date: 7/30/2019**

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# **Document Control**

## Resources

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## Project Distribution List

## Document Version Control

|  |  |  |  |
| --- | --- | --- | --- |
| **Version** | **Date** | **Modifier** | **Description** |
| V1.0 | 9/13/2016 | Art Schwartz | Originally Created |
| V1.1 | 5/30/2017 | Sarah Thies | Added Cerner Com Server Names (lab, doc & mdoc feeds) |
| V1.2 | 06/01/2017 | Dan Olszewski | Adding in modifications for Cerner Interface |
| V1.2 | 07/29/2019 | Tiffany Bohall | Updated functional requirements for Cerner Model Project |
| V1.3 | 07/30/2019 | Yitzhak Magoon | Updated document for Cerner Model |

# 1. Introduction

## 1.1 Purpose

The purpose of this document is to provide details on the build of the ORU results interface for Cerner PathNet (AP Lab) to Optum.

## 1.2 Project Scope

The scope of the integration is send ORU results from Cerner PathNet (AP Lab) to Optum

## 1.3 Terminology Standards

### 1.3.1 Acronyms

ORU - HL7 Result message

BAR – Billing account messages

### 1.3.2 Glossary

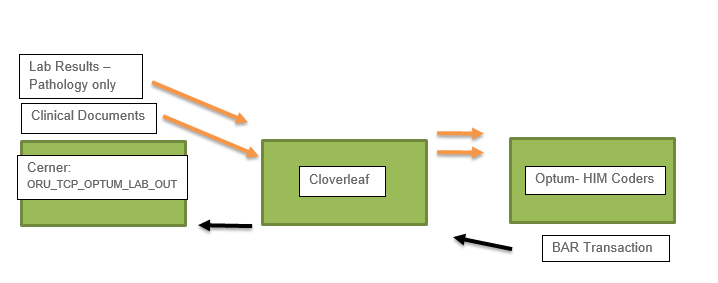
List the terms that require definition with respect to Cloverleaf and the product whose requirements are defined in this document. The definitions are specific to this document and may not be identical to the definitions of these terms in common use.

## 1.4 Document References

List all documents or Web addresses to which this IDBB refers; provide enough information so that the reader can access a copy of each reference. Include the title, author, version number, date, and source or location.

# 2. Diagram

Provide a solution diagram that depicts the integration of components specified in this IDBB. This diagram must include the data flow for the interfaces (source and target).



# 3. Requirements

## 3.1 Functional Requirements

Provide detail for the below functional requirements. The message transformation requirements for the components defined in this specification should be specified in section 4.2 of this document.

|  |  |  |
| --- | --- | --- |
| **Cloverleaf** |  |  |
| **Number** | **Requirement Name** | **Requirement Description** |
| FR.2019.07.8.1 | tpsAdvHL7Filter  (on inbound tab of source connection) | PV1.3.6 =BLM, WBH, SIP, ISU, CRC, BHO suppress  PV1.18 = MPOUTREACH, JHOUTREACH, WOOUTREACH suppress  OBR.24 =AP, continue |
| FR.2019.07.8.1 | tpsCernerLabResultsModifier  (on inbound tab of source connection) | Null PID.5.7  Null various PV1.19 visit number fields:  PV1.19.2  PV1.19.3  PV1.19.4.1  PV1.19.4.2  PV1.19.4.3  PV1.19.5  PV1.19.6.1  PV1.19.6.2  PV1.19.6.3  Swap various ORC.2 and ORC.3 fields:  ORC.2.1 and ORC.3.1  ORC.2.2 and ORC.3.2  ORC.2.3 and ORC.3.3  ORC.2.4 and ORC.3.4  Swap various OBR.2 and OBR.3 fields:  OBR.2.1 and OBR.3.1  OBR.2.2 and OBR.3.2  OBR.2.3 and OBR.3.3  OBR.2.4 and OBR.3.4  If OBX.3.3 =LOINC, swap OBX.3.4 with OBR.3.1 and swap OBX.3.5 with OBX.3.2.  Else, swap OBX.3.4 and OBX.3.1, OBX.3.5 and OBX.3.2 and OBX.3.6 and OBX.3.3. |

|  |  |  |
| --- | --- | --- |
| **Cerner** |  |  |
| **Number** | **Requirement Name** | **Requirement Description** |
| FR.2018.01.1 | **ESO Interface Trigger:**  Observation Reporting/ORU Discrete Gen Lab/CE Server GLB/GRP (CQM Class: CE) | This trigger causes the BayCare Laboratory results to be processed outbound when entered in Pathnet as long as the result items are not aliased with DONOTSEND for contributor source INVISION on code set 72.  - The following segments are set to be sent outbound by this trigger:   * HL7 MSH * HL7 PID * HL7 PV1   HL7 OBR/OBX/NTE |
| FR.2018.01.2 | Global Script:  - route\_out | route\_out (global script): Logic to route BayCare Laboratory results to the ORU\_LAB\_RESULTS\_OUT comserver. Logic is based on:   * Message Type = ORU, cqm\_type in “AP”, “MICRO”, or “GRP” * End logic for all ORU messages outbound is sent to these comservers:   - ORU\_LAB\_RESULTS\_OUT |
| FR.2019.07.29.2 | New scripts:  fsi\_common (generic)  oru\_lab\_out (mod object)  fsi\_add\_pcpe (generic) | oru \_lab\_out, Mod Object script, for BayCare Laboratory  results outbound:   * Calls the fsi\_common generic script to load all subroutines * Adds the correct ordering provider to OBR.16, the correct order name/description to OBR.4, and the correct order alias to OBR.3 for AP results. * Replace any primary care physician (PCP) with the PCP at the encounter level in the PD1 segment. * Deletes any DONOTSEND\* result items and renumbers the OBX segments accordingly. \*Note: This is a known Cerner issue where LOINC coding overrides the DONOTSEND functionality. Custom Coding was needed to fix the issue.   Filters all ORU messages if there is no OBX segment after the OBX segments are stripped as described above. |

## 3.2 Non-Functional Requirements –N/A

Provide concise detail for the below non-functional requirements. The below requirements must be evaluated for every project.

|  |  |  |
| --- | --- | --- |
| **Cloverleaf** |  |  |
| **Number** | **Requirement Name** | **Requirement Description** |
|  |  |  |
|  |  |  |

## 3.3 Messaging Protocols

Below are listed the details for the messaging protocols that will be leveraged for this integration. Please see the reference document located on the Integration SharePoint server: <insert link to document here>

### 3.3.1 Inbound from Cerner

**Test C30**

Port Number: ?

IP Address: 10.5.250.203

**Prod**

Port Number: 23388

IP Address: 10.5.250.203

Cerner Com Server ORU\_LAB\_RESULTS\_OUT port 23388 (scp749)

### 3.3.2 Outbound to Optum

**Test**

Port Number: 30098

IP Address: 161.249.96.9

**Test Stage**

Port Number: 30108

IP Address: 161.249.96.9

**Prod**

Port Number: 40108

IP Address: 161.249.96.8

# 4. HL7 Messaging

## 4.1 Messaging Format

HL7 v. 2.3, cerner\_emr ORU\_R01

### 4.1.1 Segments

The segments utilized for this interface are:

MSH

PID

[PV1]

ORC

OBR

{OBX}

*Message Construction Notes:*

*[Square Brackets] – Optional*

*{Curly Brackets} – Repeatable*

*MSH – Message Header*

*EVN – Event segment*

*PID – Patient ID segment*

*PV1 – Patient Visit segment*

*ORC – Common Order segment*

*IN1 – Insurance segment*

*[{ – Start of optional, repeatable group*

*}] – End of optional, repeatable group*

### 4.1*.*2 Messaging Event Types

Below are the messages types necessary for this integration

|  |  |
| --- | --- |
| **Event Type** | **Description** |
| ORU\_R01 | Result |

### 4.1*.*3 Cloverleaf Configuration Files

cerner\_\_optum\_oru\_soar translation file

### 4.1.4 Cloverleaf Site Location

Optum\_16

## 4.2 Data Transformation Requirements

| **Field Description** | **HL7 Field Loc.** | **Required Y/N** | **Data Type** | **Length** | **Notes** |
| --- | --- | --- | --- | --- | --- |
| MSH Segment | MSH Segment |  | Cloverleaf |  | Copy all fields |
| Receiving Application | MSH.5 | Y | Cloverleaf |  | Copy to MSH-4  Copy null to MSH-5 |
| Message Type | MSH.9 | Y | Cloverleaf |  | Change R03 to R01 in MSH-9.2 |
| Set ID | PID.1 | Y | Cloverleaf |  | copy |
| Patient ID | PID.2 | Y | Cloverleaf |  | Copy to PID-3 |
| Patient ID (Internal), Assigning Authority | PID.3.4 | Y | Cloverleaf |  | Hard coding “MRN” |
| Patient Name | PID.5 | Y | Cloverleaf |  | Copy |
| Date of Birth | PID.7 | Y | Cloverleaf |  | Copy |
| Gender | PID.8 | Y | Cloverleaf |  | Copy |
| Patient Account Number | PID.18 | Y | Cloverleaf |  | Copy |
| Attending Doctor | PV1.7 | Y | Cloverleaf |  | Copy DR when PV1-7.8 equals Baycare Doctor Number |
| Hospital service | PV1.10 | Y | Cloverleaf |  | Copy |
| Admit Source | PV1.14 | Y | Cloverleaf |  | Copy |
| Admitting Doctor | PV1.17 | Y | Cloverleaf |  | Copy DR when PV1-17.8 equals Baycare Doctor Number |
| Set -id | OBR.1 |  | Cloverleaf |  | Copy |
| Placer Number | OBR.2 |  | Cloverleaf |  | Copy |
| Filler Number | OBR.3 |  | Cloverleaf |  | Copy |
| USI | OBR.4 |  | Cloverleaf |  | Copy |
| Set ID | OBX.1 |  | Cloverleaf |  | Copy |
| Value Type | OBX.2 |  | Cloverleaf |  | Copy |
| Observation Value | OBX.5 |  | Cloverleaf |  | Copy |
| Units | OBX.6 |  | Cloverleaf |  | Copy |
| Observation results Status | OBX.11 |  | Cloverleaf |  | Copy |
| Facility code in MSH:5 | MSH.5 | Y | Cerner |  | EXECUTE OP\_MSH\_FAC\_MODOBJ\_OUT  Script to do so |
| Block all Lab except AP | OBR.24 | Y | Cerner |  | Suppress messages that don’t have “AP” as the diagnostic service. |
| Ignore patient types of: “MPOUTREACH","JHOUTREACH" | PV1.18 | Y | Cerner |  | Suppress messages with patient type of MPOUTREACH","JHOUTREACH" |
| Return the sender's order alias in OBR;19 | OBR.19 | Y | Cerner |  | Query database to pull in the order alias from the order alias table. |

## 4.3 Sample Message

**Pre-Manipulation:**

MSH|^~\&|HNAM|CERNER|INVISION|BAYCARE|20190722144138||ORU^R03|Q4432206612T5825935664||2.3||||||8859/1

PID|1|2006002074^^^BayCare MRN^MRN|2006002074^^^BayCare MRN^MRN||TESTER^AL^^^^^Current||19631104|M||||||||||1006009676^^^BayCare FIN^FIN NBR|||||||0

PV1|1|I|2N^204N^01^SFB^^Bed(s)^SFB||||MS052182^TESTER^TESTER^^^^^^BayCare Dr Number^Personnel^^^ORGANIZATION DOCTOR^CACTUS|||||||||||I|||||||||||||||||||||SFB||Active|||20190716020000

ORC|RE

OBR|1|15230362349^HNAM\_ORDERID||4902AP69^Melanoma Tumor Panel (NGS) Report|||20190717085800|20190717085800||||||||^TESTER^TESTER^^^^^^NPI Number^^^^National Provider Identifier||||00000XR20190000030^HNA\_AP\_ACCN||20190717085800||AP|F||1~^^^^^TODAY|||||&Cavida&Alyssa

OBX|1|FT|CD:2540531125^Melanoma Tumor Panel (NGS) Report^^4902AP69^Melanoma Tumor Panel (NGS) Report|| MELANOMA TUMOR PANEL (NGS) REPORT||||||F|||20190722144126

OBX|2|FT|CD:2540531125^Melanoma Tumor Panel (NGS) Report^^4902AP69^Melanoma Tumor Panel (NGS) Report||||||||F|||20190722144126

OBX|3|FT|CD:2540531125^Melanoma Tumor Panel (NGS) Report^^4902AP69^Melanoma Tumor Panel (NGS) Report||XR-19-0000030 COLLECTED DATE/TIME: 7/17/2019 08:58 EDT||||||F|||20190722144126

OBX|4|FT|CD:2540531125^Melanoma Tumor Panel (NGS) Report^^4902AP69^Melanoma Tumor Panel (NGS) Report|| RECEIVED DATE/TIME: 7/17/2019 08:58 EDT||||||F|||20190722144126

OBX|5|FT|CD:2540531125^Melanoma Tumor Panel (NGS) Report^^4902AP69^Melanoma Tumor Panel (NGS) Report||||||||F|||20190722144126

OBX|6|FT|CD:2540531125^Melanoma Tumor Panel (NGS) Report^^4902AP69^Melanoma Tumor Panel (NGS) Report||||||||F|||20190722144126

OBX|7|FT|CD:2540531125^Melanoma Tumor Panel (NGS) Report^^4902AP69^Melanoma Tumor Panel (NGS) Report||SPECIMEN||||||F|||20190722144126

OBX|8|FT|CD:2540531125^Melanoma Tumor Panel (NGS) Report^^4902AP69^Melanoma Tumor Panel (NGS) Report||||||||F|||20190722144126

OBX|9|FT|CD:2540531125^Melanoma Tumor Panel (NGS) Report^^4902AP69^Melanoma Tumor Panel (NGS) Report||FFPE Tissue||||||F|||20190722144126

OBX|10|FT|CD:2540531125^Melanoma Tumor Panel (NGS) Report^^4902AP69^Melanoma Tumor Panel (NGS) Report||||||||F|||20190722144126

OBX|11|FT|CD:2540531125^Melanoma Tumor Panel (NGS) Report^^4902AP69^Melanoma Tumor Panel (NGS) Report||MELANOMA TUMOR PANEL (NGS)||||||F|||20190722144126

OBX|12|FT|CD:2540531125^Melanoma Tumor Panel (NGS) Report^^4902AP69^Melanoma Tumor Panel (NGS) Report||POSITIVE FOR BRAF MUTATION: c.1779T>A, p.V600E||||||F|||20190722144126

OBX|13|FT|CD:2540531125^Melanoma Tumor Panel (NGS) Report^^4902AP69^Melanoma Tumor Panel (NGS) Report||||||||F|||20190722144126

OBX|14|FT|CD:2540531125^Melanoma Tumor Panel (NGS) Report^^4902AP69^Melanoma Tumor Panel (NGS) Report||||||||F|||20190722144126

OBX|15|FT|CD:2540531125^Melanoma Tumor Panel (NGS) Report^^4902AP69^Melanoma Tumor Panel (NGS) Report||Negative for Mutations within Targeted Regions of KIT and NRAS genes||||||F|||20190722144126

OBX|16|FT|CD:2540531125^Melanoma Tumor Panel (NGS) Report^^4902AP69^Melanoma Tumor Panel (NGS) Report||||||||F|||20190722144126

OBX|17|FT|CD:2540531125^Melanoma Tumor Panel (NGS) Report^^4902AP69^Melanoma Tumor Panel (NGS) Report||Gene Regions Analyzed||||||F|||20190722144126

OBX|18|FT|CD:2540531125^Melanoma Tumor Panel (NGS) Report^^4902AP69^Melanoma Tumor Panel (NGS) Report||||||||F|||20190722144126

OBX|19|FT|CD:2540531125^Melanoma Tumor Panel (NGS) Report^^4902AP69^Melanoma Tumor Panel (NGS) Report||BRAF Exon 15 (Includes Codon 600)||||||F|||20190722144126

OBX|20|FT|CD:2540531125^Melanoma Tumor Panel (NGS) Report^^4902AP69^Melanoma Tumor Panel (NGS) Report||KIT Exons 9, 11, 13, 14, 17 and 18||||||F|||20190722144126

OBX|21|FT|CD:2540531125^Melanoma Tumor Panel (NGS) Report^^4902AP69^Melanoma Tumor Panel (NGS) Report||NRAS Exons 2-3 (Includes Codons 12, 13, 59, 61)||||||F|||20190722144126

OBX|22|FT|CD:2540531125^Melanoma Tumor Panel (NGS) Report^^4902AP69^Melanoma Tumor Panel (NGS) Report||||||||F|||20190722144126

OBX|23|FT|CD:2540531125^Melanoma Tumor Panel (NGS) Report^^4902AP69^Melanoma Tumor Panel (NGS) Report||||||||F|||20190722144126

OBX|24|FT|CD:2540531125^Melanoma Tumor Panel (NGS) Report^^4902AP69^Melanoma Tumor Panel (NGS) Report||INTERPRETATION||||||F|||20190722144126

OBX|25|FT|CD:2540531125^Melanoma Tumor Panel (NGS) Report^^4902AP69^Melanoma Tumor Panel (NGS) Report||A BRAF V600E mutation is sensitive to specific kinase inhibitors, and tumors containing||||||F|||20190722144126

OBX|26|FT|CD:2540531125^Melanoma Tumor Panel (NGS) Report^^4902AP69^Melanoma Tumor Panel (NGS) Report|| this mutation may be targeted by combined BRAF and MEK inhibitors. BRAF mutations occur in||||||F|||20190722144126

OBX|27|FT|CD:2540531125^Melanoma Tumor Panel (NGS) Report^^4902AP69^Melanoma Tumor Panel (NGS) Report||||||||F|||20190722144126

OBX|28|FT|CD:2540531125^Melanoma Tumor Panel (NGS) Report^^4902AP69^Melanoma Tumor Panel (NGS) Report|| approximately 50% of melanomas and consist predominantly of V600E with a minor percentage||||||F|||20190722144126

OBX|29|FT|CD:2540531125^Melanoma Tumor Panel (NGS) Report^^4902AP69^Melanoma Tumor Panel (NGS) Report|| comprising V600K.||||||F|||20190722144126

OBX|30|FT|CD:2540531125^Melanoma Tumor Panel (NGS) Report^^4902AP69^Melanoma Tumor Panel (NGS) Report||KIT mutations occur in 15-20% of acral and mucosal melanomas and less than 5 percent of cutaneous||||||F|||20190722144126

OBX|31|FT|CD:2540531125^Melanoma Tumor Panel (NGS) Report^^4902AP69^Melanoma Tumor Panel (NGS) Report|| melanomas. The majority of KIT mutations occur in exons 11 and 13, and tumors with these||||||F|||20190722144126

OBX|32|FT|CD:2540531125^Melanoma Tumor Panel (NGS) Report^^4902AP69^Melanoma Tumor Panel (NGS) Report||||||||F|||20190722144126

OBX|33|FT|CD:2540531125^Melanoma Tumor Panel (NGS) Report^^4902AP69^Melanoma Tumor Panel (NGS) Report|| mutations may be candidates for treatment with KIT targeted tyrosine kinase inhibitors. NRAS||||||F|||20190722144126

OBX|34|FT|CD:2540531125^Melanoma Tumor Panel (NGS) Report^^4902AP69^Melanoma Tumor Panel (NGS) Report|| mutations occur in approximately 20% of melanomas and predominantly consist of mutations in||||||F|||20190722144126

OBX|35|FT|CD:2540531125^Melanoma Tumor Panel (NGS) Report^^4902AP69^Melanoma Tumor Panel (NGS) Report|| exons 2 and 3. NRAS mutations are associated with a poor prognosis. No specific inhibitor has||||||F|||20190722144126

OBX|36|FT|CD:2540531125^Melanoma Tumor Panel (NGS) Report^^4902AP69^Melanoma Tumor Panel (NGS) Report||||||||F|||20190722144126

OBX|37|FT|CD:2540531125^Melanoma Tumor Panel (NGS) Report^^4902AP69^Melanoma Tumor Panel (NGS) Report|| yet demonstrated conclusive efficacy in targeting NRAS, although NRAS mutated melanomas are an||||||F|||20190722144126

OBX|38|FT|CD:2540531125^Melanoma Tumor Panel (NGS) Report^^4902AP69^Melanoma Tumor Panel (NGS) Report|| active area of research and may be included in clinical trials.||||||F|||20190722144126

OBX|39|FT|CD:2540531125^Melanoma Tumor Panel (NGS) Report^^4902AP69^Melanoma Tumor Panel (NGS) Report||||||||F|||20190722144126

OBX|40|FT|CD:2540531125^Melanoma Tumor Panel (NGS) Report^^4902AP69^Melanoma Tumor Panel (NGS) Report||References:||||||F|||20190722144126

OBX|41|FT|CD:2540531125^Melanoma Tumor Panel (NGS) Report^^4902AP69^Melanoma Tumor Panel (NGS) Report||||||||F|||20190722144126

OBX|42|FT|CD:2540531125^Melanoma Tumor Panel (NGS) Report^^4902AP69^Melanoma Tumor Panel (NGS) Report||Boespflug, A. et al, "Treatment of NRAS-mutated advanced or metastatic melanoma: rationale,||||||F|||20190722144126

OBX|43|FT|CD:2540531125^Melanoma Tumor Panel (NGS) Report^^4902AP69^Melanoma Tumor Panel (NGS) Report|| current trials and evidence to date " (2017) Therapeutic Advances in Medical Oncology V. 9(7),||||||F|||20190722144126

OBX|44|FT|CD:2540531125^Melanoma Tumor Panel (NGS) Report^^4902AP69^Melanoma Tumor Panel (NGS) Report|| pp. 481-492.||||||F|||20190722144126

OBX|45|FT|CD:2540531125^Melanoma Tumor Panel (NGS) Report^^4902AP69^Melanoma Tumor Panel (NGS) Report||Davis, E.J. et al, "Melanoma: What do all the mutations mean? " (2018) Cancer V. 124 (17), pp.||||||F|||20190722144126

OBX|46|FT|CD:2540531125^Melanoma Tumor Panel (NGS) Report^^4902AP69^Melanoma Tumor Panel (NGS) Report||||||||F|||20190722144126

OBX|47|FT|CD:2540531125^Melanoma Tumor Panel (NGS) Report^^4902AP69^Melanoma Tumor Panel (NGS) Report|| 3490-3499.||||||F|||20190722144126

OBX|48|FT|CD:2540531125^Melanoma Tumor Panel (NGS) Report^^4902AP69^Melanoma Tumor Panel (NGS) Report||Hodi, F.S., et al, "Imatinib for melanomas harboring mutationally activated or amplified KIT||||||F|||20190722144126

OBX|49|FT|CD:2540531125^Melanoma Tumor Panel (NGS) Report^^4902AP69^Melanoma Tumor Panel (NGS) Report|| arising on mucosal, acral, and chronically sun-damaged skin " (2013) Journal of Clinical Oncology||||||F|||20190722144126

OBX|50|FT|CD:2540531125^Melanoma Tumor Panel (NGS) Report^^4902AP69^Melanoma Tumor Panel (NGS) Report||||||||F|||20190722144126

OBX|51|FT|CD:2540531125^Melanoma Tumor Panel (NGS) Report^^4902AP69^Melanoma Tumor Panel (NGS) Report|| V. 31(26) pp. 3182-3190.||||||F|||20190722144126

OBX|52|FT|CD:2540531125^Melanoma Tumor Panel (NGS) Report^^4902AP69^Melanoma Tumor Panel (NGS) Report||Long, G.V., et al, "Overall survival and durable responses in patients with BRAF V600-mutant||||||F|||20190722144126

OBX|53|FT|CD:2540531125^Melanoma Tumor Panel (NGS) Report^^4902AP69^Melanoma Tumor Panel (NGS) Report|| metastatic melanoma receiving dabrafenib combined with trametinib " (2016) Journal of Clinical||||||F|||20190722144126

OBX|54|FT|CD:2540531125^Melanoma Tumor Panel (NGS) Report^^4902AP69^Melanoma Tumor Panel (NGS) Report|| Oncology V. 34(8), pp. 871-878.||||||F|||20190722144126

OBX|55|FT|CD:2540531125^Melanoma Tumor Panel (NGS) Report^^4902AP69^Melanoma Tumor Panel (NGS) Report||||||||F|||20190722144126

OBX|56|FT|CD:2540531125^Melanoma Tumor Panel (NGS) Report^^4902AP69^Melanoma Tumor Panel (NGS) Report||||||||F|||20190722144126

OBX|57|FT|CD:2540531125^Melanoma Tumor Panel (NGS) Report^^4902AP69^Melanoma Tumor Panel (NGS) Report||METHOD||||||F|||20190722144126

OBX|58|FT|CD:2540531125^Melanoma Tumor Panel (NGS) Report^^4902AP69^Melanoma Tumor Panel (NGS) Report||A pathologist reviewed the specimen for tumor content. Genomic DNA was isolated either from the||||||F|||20190722144126

OBX|59|FT|CD:2540531125^Melanoma Tumor Panel (NGS) Report^^4902AP69^Melanoma Tumor Panel (NGS) Report|| entire specimen, or a portion of the specimen following macrodissection to enrich for tumor||||||F|||20190722144126

OBX|60|FT|CD:2540531125^Melanoma Tumor Panel (NGS) Report^^4902AP69^Melanoma Tumor Panel (NGS) Report||||||||F|||20190722144126

OBX|61|FT|CD:2540531125^Melanoma Tumor Panel (NGS) Report^^4902AP69^Melanoma Tumor Panel (NGS) Report|| content. Next generation sequencing (NGS) was performed on the Illumina MiSeq platform to||||||F|||20190722144126

OBX|62|FT|CD:2540531125^Melanoma Tumor Panel (NGS) Report^^4902AP69^Melanoma Tumor Panel (NGS) Report|| identify alterations within the following gene regions based on Genbank accession numbers,||||||F|||20190722144126

OBX|63|FT|CD:2540531125^Melanoma Tumor Panel (NGS) Report^^4902AP69^Melanoma Tumor Panel (NGS) Report||||||||F|||20190722144126

OBX|64|FT|CD:2540531125^Melanoma Tumor Panel (NGS) Report^^4902AP69^Melanoma Tumor Panel (NGS) Report||||||||F|||20190722144126

OBX|65|FT|CD:2540531125^Melanoma Tumor Panel (NGS) Report^^4902AP69^Melanoma Tumor Panel (NGS) Report|| MELANOMA TUMOR PANEL (NGS) REPORT||||||F|||20190722144126

OBX|66|FT|CD:2540531125^Melanoma Tumor Panel (NGS) Report^^4902AP69^Melanoma Tumor Panel (NGS) Report||||||||F|||20190722144126

OBX|67|FT|CD:2540531125^Melanoma Tumor Panel (NGS) Report^^4902AP69^Melanoma Tumor Panel (NGS) Report||XR-19-0000030 COLLECTED DATE/TIME: 7/17/2019 08:58 EDT||||||F|||20190722144126

OBX|68|FT|CD:2540531125^Melanoma Tumor Panel (NGS) Report^^4902AP69^Melanoma Tumor Panel (NGS) Report|| RECEIVED DATE/TIME: 7/17/2019 08:58 EDT||||||F|||20190722144126

OBX|69|FT|CD:2540531125^Melanoma Tumor Panel (NGS) Report^^4902AP69^Melanoma Tumor Panel (NGS) Report||||||||F|||20190722144126

OBX|70|FT|CD:2540531125^Melanoma Tumor Panel (NGS) Report^^4902AP69^Melanoma Tumor Panel (NGS) Report||||||||F|||20190722144126

OBX|71|FT|CD:2540531125^Melanoma Tumor Panel (NGS) Report^^4902AP69^Melanoma Tumor Panel (NGS) Report||MELANOMA TUMOR PANEL (NGS)||||||F|||20190722144126

OBX|72|FT|CD:2540531125^Melanoma Tumor Panel (NGS) Report^^4902AP69^Melanoma Tumor Panel (NGS) Report|| version hg19 (GrCH37): BRAF (NM\_004333), exon 15; KIT (NM\_000222), exons 9, 11, 13, 14, 17 and||||||F|||20190722144126

OBX|73|FT|CD:2540531125^Melanoma Tumor Panel (NGS) Report^^4902AP69^Melanoma Tumor Panel (NGS) Report||||||||F|||20190722144126

OBX|74|FT|CD:2540531125^Melanoma Tumor Panel (NGS) Report^^4902AP69^Melanoma Tumor Panel (NGS) Report|| 18; and NRAS (NM\_002524), exons 2-3. This NGS method detects single nucleotide changes as well||||||F|||20190722144126

OBX|75|FT|CD:2540531125^Melanoma Tumor Panel (NGS) Report^^4902AP69^Melanoma Tumor Panel (NGS) Report|| as small insertions and deletions. This assay does not detect chromosomal rearrangements or||||||F|||20190722144126

OBX|76|FT|CD:2540531125^Melanoma Tumor Panel (NGS) Report^^4902AP69^Melanoma Tumor Panel (NGS) Report|| gene amplifications, and it does not differentiate somatic versus germline mutations. The limit||||||F|||20190722144126

OBX|77|FT|CD:2540531125^Melanoma Tumor Panel (NGS) Report^^4902AP69^Melanoma Tumor Panel (NGS) Report|| of detection is 5% mutant allele frequency with a minimum coverage of 500 fold.||||||F|||20190722144126

OBX|78|FT|CD:2540531125^Melanoma Tumor Panel (NGS) Report^^4902AP69^Melanoma Tumor Panel (NGS) Report||||||||F|||20190722144126

OBX|79|FT|CD:2540531125^Melanoma Tumor Panel (NGS) Report^^4902AP69^Melanoma Tumor Panel (NGS) Report||This test was developed and performed and its performance characteristics determined by the||||||F|||20190722144126

OBX|80|FT|CD:2540531125^Melanoma Tumor Panel (NGS) Report^^4902AP69^Melanoma Tumor Panel (NGS) Report|| BayCare Molecular Laboratory located at 5455 W Waters Ave, Suite 208, Tampa FL 33634. It has||||||F|||20190722144126

OBX|81|FT|CD:2540531125^Melanoma Tumor Panel (NGS) Report^^4902AP69^Melanoma Tumor Panel (NGS) Report|| not been cleared or approved by the U.S. Food and Drug Administration. The FDA has determined||||||F|||20190722144126

OBX|82|FT|CD:2540531125^Melanoma Tumor Panel (NGS) Report^^4902AP69^Melanoma Tumor Panel (NGS) Report|| that such clearance or approval is not necessary. This test is used for clinical purposes. It||||||F|||20190722144126

OBX|83|FT|CD:2540531125^Melanoma Tumor Panel (NGS) Report^^4902AP69^Melanoma Tumor Panel (NGS) Report||||||||F|||20190722144126

OBX|84|FT|CD:2540531125^Melanoma Tumor Panel (NGS) Report^^4902AP69^Melanoma Tumor Panel (NGS) Report|| should not be regarded as investigational or for research. This laboratory is certified under||||||F|||20190722144126

OBX|85|FT|CD:2540531125^Melanoma Tumor Panel (NGS) Report^^4902AP69^Melanoma Tumor Panel (NGS) Report|| the Clinical Laboratory Improvement Amendments of 1988 (CLIA-88) as qualified to perform high||||||F|||20190722144126

OBX|86|FT|CD:2540531125^Melanoma Tumor Panel (NGS) Report^^4902AP69^Melanoma Tumor Panel (NGS) Report|| complexity clinical laboratory testing.||||||F|||20190722144126

OBX|87|FT|CD:2540531125^Melanoma Tumor Panel (NGS) Report^^4902AP69^Melanoma Tumor Panel (NGS) Report||||||||F|||20190722144126

OBX|88|FT|CD:2540531125^Melanoma Tumor Panel (NGS) Report^^4902AP69^Melanoma Tumor Panel (NGS) Report||CPT codes 81210, 81273, 81311||||||F|||20190722144126

OBX|89|FT|CD:2540531125^Melanoma Tumor Panel (NGS) Report^^4902AP69^Melanoma Tumor Panel (NGS) Report||Reviewed, Approved and Electronically Signed By: Cavida , Alyssa MT, FL||||||F|||20190722144126

OBX|90|FT|CD:2540531125^Melanoma Tumor Panel (NGS) Report^^4902AP69^Melanoma Tumor Panel (NGS) Report||||||||F|||20190722144126

OBX|91|FT|CD:2540531125^Melanoma Tumor Panel (NGS) Report^^4902AP69^Melanoma Tumor Panel (NGS) Report||Verified: 07/22/19 14:41 PM||||||F|||20190722144126

OBX|92|FT|CD:2540531125^Melanoma Tumor Panel (NGS) Report^^4902AP69^Melanoma Tumor Panel (NGS) Report||AC/AC||||||F|||20190722144126

**Post-Manipulation:**

MSH|^~\&|HNAM|INVISION|||20190722144138||ORU^R01|Q4432206612T58259356|P|2.4||||||8859/1

PID|1||2006002074^^^^MRN||TESTER^AL||19631104|M||||||||||1006009676

PV1|||||||MS052182^TESTER^TESTER

OBR|1||15230362349|4902AP69^Melanoma Tumor Panel (NGS) Report|||20190717085800

OBX|1|FT|CD:2540531125^Melanoma Tumor Panel (NGS) Report^^CD:2540531125^Melanoma Tumor Panel (NGS) Report|| MELANOMA TUMOR PANEL (NGS) REPORT||||||F|||20190722144126

OBX|2|FT|CD:2540531125^Melanoma Tumor Panel (NGS) Report^^CD:2540531125^Melanoma Tumor Panel (NGS) Report||||||||F|||20190722144126

OBX|3|FT|CD:2540531125^Melanoma Tumor Panel (NGS) Report^^CD:2540531125^Melanoma Tumor Panel (NGS) Report||XR-19-0000030 COLLECTED DATE/TIME: 7/17/2019 08:58 EDT||||||F|||20190722144126

OBX|4|FT|CD:2540531125^Melanoma Tumor Panel (NGS) Report^^CD:2540531125^Melanoma Tumor Panel (NGS) Report|| RECEIVED DATE/TIME: 7/17/2019 08:58 EDT||||||F|||20190722144126

OBX|5|FT|CD:2540531125^Melanoma Tumor Panel (NGS) Report^^CD:2540531125^Melanoma Tumor Panel (NGS) Report||||||||F|||20190722144126

OBX|6|FT|CD:2540531125^Melanoma Tumor Panel (NGS) Report^^CD:2540531125^Melanoma Tumor Panel (NGS) Report||||||||F|||20190722144126

OBX|7|FT|CD:2540531125^Melanoma Tumor Panel (NGS) Report^^CD:2540531125^Melanoma Tumor Panel (NGS) Report||SPECIMEN||||||F|||20190722144126

OBX|8|FT|CD:2540531125^Melanoma Tumor Panel (NGS) Report^^CD:2540531125^Melanoma Tumor Panel (NGS) Report||||||||F|||20190722144126

OBX|9|FT|CD:2540531125^Melanoma Tumor Panel (NGS) Report^^CD:2540531125^Melanoma Tumor Panel (NGS) Report||FFPE Tissue||||||F|||20190722144126

OBX|10|FT|CD:2540531125^Melanoma Tumor Panel (NGS) Report^^CD:2540531125^Melanoma Tumor Panel (NGS) Report||||||||F|||20190722144126

OBX|11|FT|CD:2540531125^Melanoma Tumor Panel (NGS) Report^^CD:2540531125^Melanoma Tumor Panel (NGS) Report||MELANOMA TUMOR PANEL (NGS)||||||F|||20190722144126

OBX|12|FT|CD:2540531125^Melanoma Tumor Panel (NGS) Report^^CD:2540531125^Melanoma Tumor Panel (NGS) Report||POSITIVE FOR BRAF MUTATION: c.1779T>A, p.V600E||||||F|||20190722144126

OBX|13|FT|CD:2540531125^Melanoma Tumor Panel (NGS) Report^^CD:2540531125^Melanoma Tumor Panel (NGS) Report||||||||F|||20190722144126

OBX|14|FT|CD:2540531125^Melanoma Tumor Panel (NGS) Report^^CD:2540531125^Melanoma Tumor Panel (NGS) Report||||||||F|||20190722144126

OBX|15|FT|CD:2540531125^Melanoma Tumor Panel (NGS) Report^^CD:2540531125^Melanoma Tumor Panel (NGS) Report||Negative for Mutations within Targeted Regions of KIT and NRAS genes||||||F|||20190722144126

OBX|16|FT|CD:2540531125^Melanoma Tumor Panel (NGS) Report^^CD:2540531125^Melanoma Tumor Panel (NGS) Report||||||||F|||20190722144126

OBX|17|FT|CD:2540531125^Melanoma Tumor Panel (NGS) Report^^CD:2540531125^Melanoma Tumor Panel (NGS) Report||Gene Regions Analyzed||||||F|||20190722144126

OBX|18|FT|CD:2540531125^Melanoma Tumor Panel (NGS) Report^^CD:2540531125^Melanoma Tumor Panel (NGS) Report||||||||F|||20190722144126

OBX|19|FT|CD:2540531125^Melanoma Tumor Panel (NGS) Report^^CD:2540531125^Melanoma Tumor Panel (NGS) Report||BRAF Exon 15 (Includes Codon 600)||||||F|||20190722144126

OBX|20|FT|CD:2540531125^Melanoma Tumor Panel (NGS) Report^^CD:2540531125^Melanoma Tumor Panel (NGS) Report||KIT Exons 9, 11, 13, 14, 17 and 18||||||F|||20190722144126

OBX|21|FT|CD:2540531125^Melanoma Tumor Panel (NGS) Report^^CD:2540531125^Melanoma Tumor Panel (NGS) Report||NRAS Exons 2-3 (Includes Codons 12, 13, 59, 61)||||||F|||20190722144126

OBX|22|FT|CD:2540531125^Melanoma Tumor Panel (NGS) Report^^CD:2540531125^Melanoma Tumor Panel (NGS) Report||||||||F|||20190722144126

OBX|23|FT|CD:2540531125^Melanoma Tumor Panel (NGS) Report^^CD:2540531125^Melanoma Tumor Panel (NGS) Report||||||||F|||20190722144126

OBX|24|FT|CD:2540531125^Melanoma Tumor Panel (NGS) Report^^CD:2540531125^Melanoma Tumor Panel (NGS) Report||INTERPRETATION||||||F|||20190722144126

OBX|25|FT|CD:2540531125^Melanoma Tumor Panel (NGS) Report^^CD:2540531125^Melanoma Tumor Panel (NGS) Report||A BRAF V600E mutation is sensitive to specific kinase inhibitors, and tumors containing||||||F|||20190722144126

OBX|26|FT|CD:2540531125^Melanoma Tumor Panel (NGS) Report^^CD:2540531125^Melanoma Tumor Panel (NGS) Report|| this mutation may be targeted by combined BRAF and MEK inhibitors. BRAF mutations occur in||||||F|||20190722144126

OBX|27|FT|CD:2540531125^Melanoma Tumor Panel (NGS) Report^^CD:2540531125^Melanoma Tumor Panel (NGS) Report||||||||F|||20190722144126

OBX|28|FT|CD:2540531125^Melanoma Tumor Panel (NGS) Report^^CD:2540531125^Melanoma Tumor Panel (NGS) Report|| approximately 50% of melanomas and consist predominantly of V600E with a minor percentage||||||F|||20190722144126

OBX|29|FT|CD:2540531125^Melanoma Tumor Panel (NGS) Report^^CD:2540531125^Melanoma Tumor Panel (NGS) Report|| comprising V600K.||||||F|||20190722144126

OBX|30|FT|CD:2540531125^Melanoma Tumor Panel (NGS) Report^^CD:2540531125^Melanoma Tumor Panel (NGS) Report||KIT mutations occur in 15-20% of acral and mucosal melanomas and less than 5 percent of cutaneous||||||F|||20190722144126

OBX|31|FT|CD:2540531125^Melanoma Tumor Panel (NGS) Report^^CD:2540531125^Melanoma Tumor Panel (NGS) Report|| melanomas. The majority of KIT mutations occur in exons 11 and 13, and tumors with these||||||F|||20190722144126

OBX|32|FT|CD:2540531125^Melanoma Tumor Panel (NGS) Report^^CD:2540531125^Melanoma Tumor Panel (NGS) Report||||||||F|||20190722144126

OBX|33|FT|CD:2540531125^Melanoma Tumor Panel (NGS) Report^^CD:2540531125^Melanoma Tumor Panel (NGS) Report|| mutations may be candidates for treatment with KIT targeted tyrosine kinase inhibitors. NRAS||||||F|||20190722144126

OBX|34|FT|CD:2540531125^Melanoma Tumor Panel (NGS) Report^^CD:2540531125^Melanoma Tumor Panel (NGS) Report|| mutations occur in approximately 20% of melanomas and predominantly consist of mutations in||||||F|||20190722144126

OBX|35|FT|CD:2540531125^Melanoma Tumor Panel (NGS) Report^^CD:2540531125^Melanoma Tumor Panel (NGS) Report|| exons 2 and 3. NRAS mutations are associated with a poor prognosis. No specific inhibitor has||||||F|||20190722144126

OBX|36|FT|CD:2540531125^Melanoma Tumor Panel (NGS) Report^^CD:2540531125^Melanoma Tumor Panel (NGS) Report||||||||F|||20190722144126

OBX|37|FT|CD:2540531125^Melanoma Tumor Panel (NGS) Report^^CD:2540531125^Melanoma Tumor Panel (NGS) Report|| yet demonstrated conclusive efficacy in targeting NRAS, although NRAS mutated melanomas are an||||||F|||20190722144126

OBX|38|FT|CD:2540531125^Melanoma Tumor Panel (NGS) Report^^CD:2540531125^Melanoma Tumor Panel (NGS) Report|| active area of research and may be included in clinical trials.||||||F|||20190722144126

OBX|39|FT|CD:2540531125^Melanoma Tumor Panel (NGS) Report^^CD:2540531125^Melanoma Tumor Panel (NGS) Report||||||||F|||20190722144126

OBX|40|FT|CD:2540531125^Melanoma Tumor Panel (NGS) Report^^CD:2540531125^Melanoma Tumor Panel (NGS) Report||References:||||||F|||20190722144126

OBX|41|FT|CD:2540531125^Melanoma Tumor Panel (NGS) Report^^CD:2540531125^Melanoma Tumor Panel (NGS) Report||||||||F|||20190722144126

OBX|42|FT|CD:2540531125^Melanoma Tumor Panel (NGS) Report^^CD:2540531125^Melanoma Tumor Panel (NGS) Report||Boespflug, A. et al, "Treatment of NRAS-mutated advanced or metastatic melanoma: rationale,||||||F|||20190722144126

OBX|43|FT|CD:2540531125^Melanoma Tumor Panel (NGS) Report^^CD:2540531125^Melanoma Tumor Panel (NGS) Report|| current trials and evidence to date " (2017) Therapeutic Advances in Medical Oncology V. 9(7),||||||F|||20190722144126

OBX|44|FT|CD:2540531125^Melanoma Tumor Panel (NGS) Report^^CD:2540531125^Melanoma Tumor Panel (NGS) Report|| pp. 481-492.||||||F|||20190722144126

OBX|45|FT|CD:2540531125^Melanoma Tumor Panel (NGS) Report^^CD:2540531125^Melanoma Tumor Panel (NGS) Report||Davis, E.J. et al, "Melanoma: What do all the mutations mean? " (2018) Cancer V. 124 (17), pp.||||||F|||20190722144126

OBX|46|FT|CD:2540531125^Melanoma Tumor Panel (NGS) Report^^CD:2540531125^Melanoma Tumor Panel (NGS) Report||||||||F|||20190722144126

OBX|47|FT|CD:2540531125^Melanoma Tumor Panel (NGS) Report^^CD:2540531125^Melanoma Tumor Panel (NGS) Report|| 3490-3499.||||||F|||20190722144126

OBX|48|FT|CD:2540531125^Melanoma Tumor Panel (NGS) Report^^CD:2540531125^Melanoma Tumor Panel (NGS) Report||Hodi, F.S., et al, "Imatinib for melanomas harboring mutationally activated or amplified KIT||||||F|||20190722144126

OBX|49|FT|CD:2540531125^Melanoma Tumor Panel (NGS) Report^^CD:2540531125^Melanoma Tumor Panel (NGS) Report|| arising on mucosal, acral, and chronically sun-damaged skin " (2013) Journal of Clinical Oncology||||||F|||20190722144126

OBX|50|FT|CD:2540531125^Melanoma Tumor Panel (NGS) Report^^CD:2540531125^Melanoma Tumor Panel (NGS) Report||||||||F|||20190722144126

OBX|51|FT|CD:2540531125^Melanoma Tumor Panel (NGS) Report^^CD:2540531125^Melanoma Tumor Panel (NGS) Report|| V. 31(26) pp. 3182-3190.||||||F|||20190722144126

OBX|52|FT|CD:2540531125^Melanoma Tumor Panel (NGS) Report^^CD:2540531125^Melanoma Tumor Panel (NGS) Report||Long, G.V., et al, "Overall survival and durable responses in patients with BRAF V600-mutant||||||F|||20190722144126

OBX|53|FT|CD:2540531125^Melanoma Tumor Panel (NGS) Report^^CD:2540531125^Melanoma Tumor Panel (NGS) Report|| metastatic melanoma receiving dabrafenib combined with trametinib " (2016) Journal of Clinical||||||F|||20190722144126

OBX|54|FT|CD:2540531125^Melanoma Tumor Panel (NGS) Report^^CD:2540531125^Melanoma Tumor Panel (NGS) Report|| Oncology V. 34(8), pp. 871-878.||||||F|||20190722144126

OBX|55|FT|CD:2540531125^Melanoma Tumor Panel (NGS) Report^^CD:2540531125^Melanoma Tumor Panel (NGS) Report||||||||F|||20190722144126

OBX|56|FT|CD:2540531125^Melanoma Tumor Panel (NGS) Report^^CD:2540531125^Melanoma Tumor Panel (NGS) Report||||||||F|||20190722144126

OBX|57|FT|CD:2540531125^Melanoma Tumor Panel (NGS) Report^^CD:2540531125^Melanoma Tumor Panel (NGS) Report||METHOD||||||F|||20190722144126

OBX|58|FT|CD:2540531125^Melanoma Tumor Panel (NGS) Report^^CD:2540531125^Melanoma Tumor Panel (NGS) Report||A pathologist reviewed the specimen for tumor content. Genomic DNA was isolated either from the||||||F|||20190722144126

OBX|59|FT|CD:2540531125^Melanoma Tumor Panel (NGS) Report^^CD:2540531125^Melanoma Tumor Panel (NGS) Report|| entire specimen, or a portion of the specimen following macrodissection to enrich for tumor||||||F|||20190722144126

OBX|60|FT|CD:2540531125^Melanoma Tumor Panel (NGS) Report^^CD:2540531125^Melanoma Tumor Panel (NGS) Report||||||||F|||20190722144126

OBX|61|FT|CD:2540531125^Melanoma Tumor Panel (NGS) Report^^CD:2540531125^Melanoma Tumor Panel (NGS) Report|| content. Next generation sequencing (NGS) was performed on the Illumina MiSeq platform to||||||F|||20190722144126

OBX|62|FT|CD:2540531125^Melanoma Tumor Panel (NGS) Report^^CD:2540531125^Melanoma Tumor Panel (NGS) Report|| identify alterations within the following gene regions based on Genbank accession numbers,||||||F|||20190722144126

OBX|63|FT|CD:2540531125^Melanoma Tumor Panel (NGS) Report^^CD:2540531125^Melanoma Tumor Panel (NGS) Report||||||||F|||20190722144126

OBX|64|FT|CD:2540531125^Melanoma Tumor Panel (NGS) Report^^CD:2540531125^Melanoma Tumor Panel (NGS) Report||||||||F|||20190722144126

OBX|65|FT|CD:2540531125^Melanoma Tumor Panel (NGS) Report^^CD:2540531125^Melanoma Tumor Panel (NGS) Report|| MELANOMA TUMOR PANEL (NGS) REPORT||||||F|||20190722144126

OBX|66|FT|CD:2540531125^Melanoma Tumor Panel (NGS) Report^^CD:2540531125^Melanoma Tumor Panel (NGS) Report||||||||F|||20190722144126

OBX|67|FT|CD:2540531125^Melanoma Tumor Panel (NGS) Report^^CD:2540531125^Melanoma Tumor Panel (NGS) Report||XR-19-0000030 COLLECTED DATE/TIME: 7/17/2019 08:58 EDT||||||F|||20190722144126

OBX|68|FT|CD:2540531125^Melanoma Tumor Panel (NGS) Report^^CD:2540531125^Melanoma Tumor Panel (NGS) Report|| RECEIVED DATE/TIME: 7/17/2019 08:58 EDT||||||F|||20190722144126

OBX|69|FT|CD:2540531125^Melanoma Tumor Panel (NGS) Report^^CD:2540531125^Melanoma Tumor Panel (NGS) Report||||||||F|||20190722144126

OBX|70|FT|CD:2540531125^Melanoma Tumor Panel (NGS) Report^^CD:2540531125^Melanoma Tumor Panel (NGS) Report||||||||F|||20190722144126

OBX|71|FT|CD:2540531125^Melanoma Tumor Panel (NGS) Report^^CD:2540531125^Melanoma Tumor Panel (NGS) Report||MELANOMA TUMOR PANEL (NGS)||||||F|||20190722144126

OBX|72|FT|CD:2540531125^Melanoma Tumor Panel (NGS) Report^^CD:2540531125^Melanoma Tumor Panel (NGS) Report|| version hg19 (GrCH37): BRAF (NM\_004333), exon 15; KIT (NM\_000222), exons 9, 11, 13, 14, 17 and||||||F|||20190722144126

OBX|73|FT|CD:2540531125^Melanoma Tumor Panel (NGS) Report^^CD:2540531125^Melanoma Tumor Panel (NGS) Report||||||||F|||20190722144126

OBX|74|FT|CD:2540531125^Melanoma Tumor Panel (NGS) Report^^CD:2540531125^Melanoma Tumor Panel (NGS) Report|| 18; and NRAS (NM\_002524), exons 2-3. This NGS method detects single nucleotide changes as well||||||F|||20190722144126

OBX|75|FT|CD:2540531125^Melanoma Tumor Panel (NGS) Report^^CD:2540531125^Melanoma Tumor Panel (NGS) Report|| as small insertions and deletions. This assay does not detect chromosomal rearrangements or||||||F|||20190722144126

OBX|76|FT|CD:2540531125^Melanoma Tumor Panel (NGS) Report^^CD:2540531125^Melanoma Tumor Panel (NGS) Report|| gene amplifications, and it does not differentiate somatic versus germline mutations. The limit||||||F|||20190722144126

OBX|77|FT|CD:2540531125^Melanoma Tumor Panel (NGS) Report^^CD:2540531125^Melanoma Tumor Panel (NGS) Report|| of detection is 5% mutant allele frequency with a minimum coverage of 500 fold.||||||F|||20190722144126

OBX|78|FT|CD:2540531125^Melanoma Tumor Panel (NGS) Report^^CD:2540531125^Melanoma Tumor Panel (NGS) Report||||||||F|||20190722144126

OBX|79|FT|CD:2540531125^Melanoma Tumor Panel (NGS) Report^^CD:2540531125^Melanoma Tumor Panel (NGS) Report||This test was developed and performed and its performance characteristics determined by the||||||F|||20190722144126

OBX|80|FT|CD:2540531125^Melanoma Tumor Panel (NGS) Report^^CD:2540531125^Melanoma Tumor Panel (NGS) Report|| BayCare Molecular Laboratory located at 5455 W Waters Ave, Suite 208, Tampa FL 33634. It has||||||F|||20190722144126

OBX|81|FT|CD:2540531125^Melanoma Tumor Panel (NGS) Report^^CD:2540531125^Melanoma Tumor Panel (NGS) Report|| not been cleared or approved by the U.S. Food and Drug Administration. The FDA has determined||||||F|||20190722144126

OBX|82|FT|CD:2540531125^Melanoma Tumor Panel (NGS) Report^^CD:2540531125^Melanoma Tumor Panel (NGS) Report|| that such clearance or approval is not necessary. This test is used for clinical purposes. It||||||F|||20190722144126

OBX|83|FT|CD:2540531125^Melanoma Tumor Panel (NGS) Report^^CD:2540531125^Melanoma Tumor Panel (NGS) Report||||||||F|||20190722144126

OBX|84|FT|CD:2540531125^Melanoma Tumor Panel (NGS) Report^^CD:2540531125^Melanoma Tumor Panel (NGS) Report|| should not be regarded as investigational or for research. This laboratory is certified under||||||F|||20190722144126

OBX|85|FT|CD:2540531125^Melanoma Tumor Panel (NGS) Report^^CD:2540531125^Melanoma Tumor Panel (NGS) Report|| the Clinical Laboratory Improvement Amendments of 1988 (CLIA-88) as qualified to perform high||||||F|||20190722144126

OBX|86|FT|CD:2540531125^Melanoma Tumor Panel (NGS) Report^^CD:2540531125^Melanoma Tumor Panel (NGS) Report|| complexity clinical laboratory testing.||||||F|||20190722144126

OBX|87|FT|CD:2540531125^Melanoma Tumor Panel (NGS) Report^^CD:2540531125^Melanoma Tumor Panel (NGS) Report||||||||F|||20190722144126

OBX|88|FT|CD:2540531125^Melanoma Tumor Panel (NGS) Report^^CD:2540531125^Melanoma Tumor Panel (NGS) Report||CPT codes 81210, 81273, 81311||||||F|||20190722144126

OBX|89|FT|CD:2540531125^Melanoma Tumor Panel (NGS) Report^^CD:2540531125^Melanoma Tumor Panel (NGS) Report||Reviewed, Approved and Electronically Signed By: Cavida , Alyssa MT, FL||||||F|||20190722144126

OBX|90|FT|CD:2540531125^Melanoma Tumor Panel (NGS) Report^^CD:2540531125^Melanoma Tumor Panel (NGS) Report||||||||F|||20190722144126

OBX|91|FT|CD:2540531125^Melanoma Tumor Panel (NGS) Report^^CD:2540531125^Melanoma Tumor Panel (NGS) Report||Verified: 07/22/19 14:41 PM||||||F|||20190722144126

OBX|92|FT|CD:2540531125^Melanoma Tumor Panel (NGS) Report^^CD:2540531125^Melanoma Tumor Panel (NGS) Report||AC/AC||||||F|||20190722144126

# **5. Testing –N/A**

## 5.1. Unit Testing Scenarios

|  |  |
| --- | --- |
| **Scenario** | **Expected Result** |
|  |  |
|  |  |
|  |  |
|  |  |
|  |  |

## 5.2 Integrated Testing Scenarios

|  |  |
| --- | --- |
| **Scenario** | **Expected Result** |
|  |  |
|  |  |
|  |  |

## 5.3 Testing Approvals

|  |  |  |  |
| --- | --- | --- | --- |
| **Testing Phase** | **Date** | **Department** | **Team Member** |
|  |  |  |  |
|  |  |  |  |

## 5.4 Piloting

N/A

## 5.5 Approvals

|  |  |  |  |
| --- | --- | --- | --- |
| **Testing Phase** | **Date** | **Department** | **Team Member** |
| PH1.0 |  |  |  |
|  |  |  |  |
|  |  |  |  |

# Appendix A: Risks and Concerns

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Project Name** |  |  | | |  |  |  |  |
| **Number** | **Risk / Concern** | **Comment** | **Mitigation** | | |  |  |  |
| RC.2013.1.0 |  |  | |  | |  |  |  |

# Appendix B: Issues List

This is a dynamic list of the open issues related to the IDBB that remain to be solved, including but not limited to TBDs, pending decisions, information needed, conflict awaiting resolution, and the like.

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Project Name** |  |  | | |  |  |  |  |
| **Number** | **Issue** | **Comment** | **Fix** | | |  |  |  |
| I.2013.1.0 |  |  | |  | |  |  |  |

* End of document