







LAB Dept MEETING – Huddles

Date of Meeting: April 6, 2021

Attendees: Juanita Fernandez, Juliet Garlejo, Marietes Gonzalez, Yetunde Kosoko, Raquel Lecaro, Melanie Magee, Lourdes Maniago, Mariela Mora, Sumera Nazir, Myrna Ocob, Erica Torres, Michelle Trammell, Patricia Chea, Marissa Calilung, Theda

Topic	Details	Action Item, responsible person, date due, or informational only							
SAFETY TIP	<p>This red biohazard bin is full up to the brim. Don't let waste go up that high, must be only up to 75% full.</p> 	Informational							
KUDOS	<p>3rd and 4th Quarter Perfect Attendance</p> <table border="1" data-bbox="446 1020 1133 1306"> <thead> <tr> <th data-bbox="446 1020 1133 1062">EMPLOYEE</th> </tr> </thead> <tbody> <tr> <td data-bbox="446 1062 1133 1104">Erica Torres</td> </tr> <tr> <td data-bbox="446 1104 1133 1146">Lourdes Q. Maniago</td> </tr> <tr> <td data-bbox="446 1146 1133 1188">Nancy Khalil Fahiem Khalil</td> </tr> <tr> <td data-bbox="446 1188 1133 1230">Raquel A Lecaro</td> </tr> <tr> <td data-bbox="446 1230 1133 1272">Sumera Nazir</td> </tr> <tr> <td data-bbox="446 1272 1133 1306">Yetunde Folashade Kosoko</td> </tr> </tbody> </table>	EMPLOYEE	Erica Torres	Lourdes Q. Maniago	Nancy Khalil Fahiem Khalil	Raquel A Lecaro	Sumera Nazir	Yetunde Folashade Kosoko	
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<p>Lab Week- to move week of April 26 due to CAP inspection.</p>	<div style="text-align: center;"> <p>GET READY!!!!</p> <p>2021 Lab Week April 19th-23rd</p> <p><u>Themes /Games/Food</u> this year are:</p> </div> <div style="display: flex; justify-content: space-around;"> <div style="text-align: center;"> <p>Monday- Music Monday (Favorite band T-shirt)</p> <p>Guess that kazoo song/Cinnabon</p>  </div> <div style="text-align: center;"> <p>Tuesday- Tie Dye</p> <p>Hip-pea in a cup/B-fast Burritos</p>  </div> </div> <div style="display: flex; justify-content: space-around; margin-top: 20px;"> <div style="text-align: center;"> <p>Wednesday- Silly Hat/Hair day</p> <p>Most creative and silliest wins prize/ Sandwiches (WEAR YOUR LAB SWEATSHIRT)</p>  </div> <div style="text-align: center;"> <p>Thursday- 80's Day</p> <p>80's Trivia/Totally Tubular Pizza</p>  </div> </div> <div style="text-align: center; margin-top: 20px;"> <p>Friday- The lab is a Zoo!! Day</p> <p>Hungry Hungry Hippo Face off/ Bucket O' Fun</p>  </div>	<p>ALL STAFF</p>
<p>COBAS testing alert.</p>	<ul style="list-style-type: none"> • .COBAS LIAT Technical Bulletin <ul style="list-style-type: none"> ✓ Any unusual error messages such as “Thermal runaway” – stop testing and report to manager ✓ Any unusually high invalid result- stop testing and report to manager ✓ Any increase in Flu B positive result- stop testing and report to manager ✓ See technical bulletin attached and on the hood 	<p>CLS</p>
<p>Cerner Comments can now be read by members.</p>	<p>Dear CLS</p> <p>In our response to the 21st Century Cures Act, all comments in Cerner are now visible to our members.</p> <p>Make sure to follow policy in writing comments.</p> <p>Any additional information that is outside the policy or canned comments- use Cerner Order NOTES or Result NOTES.</p> <p>Example, if you want to document that you called Pharmacy twice and no response- document that under NOTES.</p>	<p>CLS</p>

**Chino will fax
this document-
give to SPA
Phlebotomist**

**Phleb to perform
problem solving,
document on the
form, then file.**

**Do not ignore the
fax machine or
leave in manager
mailbox.**

**It must be
addressed right
away**

Mar/6/2021 10:18:01 PM KP Bacteriology->9512516722 1/1
2021-03-06 22:09 KP Bacteriology 9097036030 >> 9512516722 P 1/1
Medical Care Program California Division - South RRL-Chino Hills Record

BACTERIOLOGY SPECIMEN PROBLEM FORM

To: SUPERVISOR Facility: Moreno Valley Area
From: RRL-CH BACTERIOLOGY DEPT. Phone: (Tie Line) 8-263-6056 FAX: (Tie Line) 8-263-6035

Patient Name: HERNANDEZ, DANIEL RT 23-AUG-1989 Medical Record #: _____ Physician: _____
Accession #: 2-21-065-032610 Date and Time of Collection: _____ @ _____
Location: BC Time of Receipt: _____ @ _____
Specimen Received: Whole Blood [specify anticoagulant: _____] Serum Fluid [specify] _____ IVD Digene
Clotted Blood [specify: SST Non-SST Spun Unspun] _____ BD E-Swab
Universal Transport Media CT/GC Transporter Stool [specify: _____] BD Vacutainer (gray top)
Plated media [specify: _____]
Other [specify: _____]
Test(s) Ordered: _____

ACCESSIONING ERROR	ADDITIONAL INFORMATION REQUIRED	UNABLE TO PERFORM TEST PLEASE RESUBMIT
<ul style="list-style-type: none"> Wrong Gender Wrong anatomical data Wrong medical record number/name Wrong test accessioned Different name (AKA) Not of File: <ul style="list-style-type: none"> Barcode of specimen; not accessioned NOF No barcode on specimen [NBC] Accessioned for wrong performing Facility [WFF] Incomplete accessioning Delete Reason: <div style="border: 1px solid black; padding: 2px; width: fit-content;"> PLEASE RESPOND WITHIN 48-HOURS ! OTHERWISE, SPECIMEN WILL BE DISCARDED </div> 	<ul style="list-style-type: none"> Provider not specified; please indicate _____ Test not specified; please indicate test(s) Requested: _____ Please specify source/body site: _____ Total Volume _____ mL Status of patient: <ul style="list-style-type: none"> < 12 years ≥ 12 years Other: WOULD YOU LIKE TO ORDER 	<ul style="list-style-type: none"> Mismatch [name on specimen does not Match name on slip/collection label] QNS [quantity not sufficient] Unacceptable specimen Uninoculated media Incorrect media Other: _____ Specimen received in biohazardous Condition [unable to process] Lab accident/Lab error [describe: _____] No Specimen received Other: _____

(ANCILLARY SERVICES DEPARTMENT USE ONLY)

Ordering facility called Date/Time: _____ Person notified _____
Problem Form faxed to ordering facility _____ Specimen(s) returned per request _____ Specimen(s) discarded _____
Test(s) performed _____ Test(s) deleted _____ Specimen on hold _____
Resolution: _____
Completed by: Initials CL Date: 3/6/21 Clerk Lab Assistant CLS Supervisor _____
Document No: LUL 0084A Page 1 of 1 Version No: 02

Phlebotomist

UBT

This concludes the Minutes of the April 6, 2021 Lab Staff Meeting.

Prepared by: Patricia Chea, Marissa Calilung Date: 6/2/2021

Technical Bulletin

Laboratory Care Delivery System

SPORADIC FALSE POSITIVE RAPID MOLECULAR FLUID RESULTS

Roche recently identified some sporadic false positive results associated with their cobas Liat SARS-CoV-2 + Influenza A/B molecular multiplex test (**SARS COV-2 (COVID-19), INFLUENZA A + B, MULTIPLEX NAA [87636A]**), particularly for the Influenza B target. They proactively reported these events to the FDA and are conducting an in-depth investigation to fully understand the cause and to determine next steps.

According to the FDA, the false positive results may be related to two issues observed by Roche:

- Roche identified that the assay tubes may sporadically leak, causing an obstructed optical path in the Liat analyzer, producing abnormal PCR growth curves. This could lead to invalid or erroneous positive results, particularly for the Flu B test. If a tube leak occurs, later testing runs may have an increased likelihood of false positive Flu B results.
- Roche determined that abnormal PCR cycling in the reaction tubes may also produce abnormal PCR growth curves, leading to erroneous results. The issue is sporadic and may be caused by multiple factors happening at the same time, such as hardware positioning, volume movement, and curve interpretation. This issue may cause false positive results for multiple analytes (Influenza A, Influenza B and/or SARS-CoV-2) in a single testing run.

The FDA recommends users of the cobas SARS-CoV-2 & Influenza A/B Nucleic Acid Test for use on the cobas Liat System:

- Monitor for unexpected clusters of positive Flu B results, as this may indicate the cobas Liat System has experienced a tube leak.
- Repeat tests when two or three analytes are positive. Different results on the repeat test may indicate abnormal PCR cycling.
- Stop using the cobas Liat System and contact Roche if you suspect either of these two issues has occurred.

In addition to following the FDA recommendations above, the LCDS will send repeatedly multi-analyte positive results to the RRL for confirmation testing by way of the following assay: **SARS-COV-2 (COVID-19), INFLUENZA A, INFLUENZA B, MULTIPLEX NAA, HIGH THROUGHPUT [258971]**.

QUESTIONS?

- Client Service Center: 1-888-4LAB NFO, or tie line 8-397-7077
- Jonathan C. Gullett, MD, Physician Director of Microbiology, jonathan.c.gullett@kp.org
- Ken Van Horn, PhD, D(ABMM), Technical Director of Microbiology, ken.van-horn@kp.org
- Tam Van, PhD, D(ABMM); Technical Director of Microbiology, tam.t.van@kp.org

Technical Bulletins are archived on **LABNET** for your convenience.
<http://kpnet.kp.org:81/california/scpmsg/labnet/index.htm>



Technical Bulletin

Laboratory Care Delivery System

CHANGES TO RAPID RESPIRATORY SYNCYTIAL VIRUS (RSV) TESTING

Effective Wednesday, **March 31, 2021**, the Laboratory Care Delivery System will make the following changes to rapid RSV testing:

- **RAPID INFLUENZA A/B AND RSV, PCR [87631C]** will be discontinued temporarily due to vendor supply issues.
- Instead, **RSV ANTIGEN SCREEN [87807A]** will be performed using the BD Veritor antigen detection system at local Medical Center Laboratories.

There will be no changes to the **RAPID INFLUENZA A/B, PCR [87502A]** or **SARS COV-2 (COVID-19), INFLUENZA A + B, MULTIPLEX NAA [87636A]** orderables. Select MOBs and EDs that are already using the BD Veritor for point-of-care RSV (**RSV ANTIGEN, NASAL SWAB, IMMUNOASSAY, POCT [87807D]**) and/or Influenza (**INFLUENZA VIRUS ANTIGEN (A, B), NASAL SWAB, POCT [87804D]**) testing can continue to do so.

TEST INFORMATION

KPHC Order Display Name [Code]	RSV ANTIGEN SCREEN [87807A]		
KRMS Procedure Name [Code]	RSV SCREEN [8649677]		
Test Location	Medical Center Laboratories		
CPT Code(s)	87807		
Specimen Requirement	Nasopharyngeal swab in UVT/UTM		
Transport Temperature	Refrigerated (2-8°C)		
Stability	72 hrs		
Special Instructions	This test is intended for <i>in vitro</i> diagnostic use to aid in the diagnosis of RSV infections in infants and pediatric patients under the age of 20 years.		
KPHC Result Components	Display Name	CID	Base Name
	RSV AG	12121039	RSVAG

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- Tam Van, PhD, D(ABMM); Technical Director of Microbiology, tam.t.van@kp.org

Technical Bulletin

Laboratory Care Delivery System

BLOOD CULTURE CONTAMINATION REPORT CHANGES

The Laboratory Care Delivery System is pleased to announce that monthly Blood Culture Contamination Reports have been revised to include a more accurate count of true contaminants and will now be more readily available electronically. Reports should be available within the first week of each month and posted on [SharePoint](#), where current reports are located. January and February 2021 reports have already been posted.

Specific existing changes include:

- The Contamination report, which is derived from iLab data, resides in SharePoint, and published each month.
- Revision of the previous acceptable contamination rate from existing ($\leq 2\%$) to microbiology standard ($\leq 3\%$)
- More accurate capture of contaminant organisms / events
- More accurate capture of draw location and collecting individual (where available)

Additional changes to soon follow:

- Procedure for report to be posted on SharePoint
- Electronic form for Med Center documentation/review available, and relevant corrective actions that need to be taken

There will be only minimal changes to the actual structure of the report.

QUESTIONS?

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- Jonathan C. Gullett, MD, Physician Director of Microbiology, jonathan.c.gullett@kp.org
- Ken Van Horn, PhD, D(ABMM), Technical Director of Microbiology, ken.van-horn@kp.org
- Tam Van, PhD, D(ABMM); Technical Director of Microbiology, tam.t.van@kp.org



URGENT MEDICAL DEVICE CORRECTION

cobas® SARS-CoV-2 & Influenza A/B Assay for Use Under Emergency Use Authorization – Potential for Invalid or False Positive Results

This Urgent Medical Device Correction (UMDC) only affects customers using:

Product	Analyzer	Catalog Number
cobas® Liat® analyzer	All serial ID numbers	07341920190
cobas SARS-CoV-2 & Influenza A/B assay	cobas Liat	09211101190

Issue

Recently, Roche discovered and proactively shared an issue with the FDA regarding invalid or false positive results for one or more targets (SARS-CoV-2/Influenza A/Influenza B) using the **cobas** SARS-CoV-2 & Influenza A/B assay for use under emergency use authorization on the **cobas** Liat analyzer. A review of customer-provided data associated with the reported invalid or false positive results showed abnormal PCR growth curves.

Actions Required

- Inform any operators that use the **cobas** Liat analyzer and/or **cobas** SARS-CoV-2 & Influenza A/B test of the potential hazards associated with this issue and provide a copy of this UMDC as appropriate.
- If you observe an increase in Influenza B positive results that does not match community infection rates, stop testing on the **cobas** Liat analyzer and contact the Roche Support Network Customer Support Center at 1-800-800-5973 to determine if a tube leak or other issue has occurred.
- If you observe dual- and/or triple-positive results for a particular sample, retest the sample with the **cobas** SARS-CoV-2 & Influenza A/B test for use with the **cobas** Liat analyzer using a different **cobas** Liat analyzer. If you do not have an additional analyzer or if results on the second analyzer disagree with the results from the first analyzer, stop testing on the affected analyzer and contact the Roche Support Network Customer Support Center at 1-800-800-5973.
- Monitor your invalid result rates. If there is a sudden increase or if invalid results are observed repeatedly on a specific **cobas** Liat analyzer, stop testing on the analyzer and contact the Roche Support Network Customer Support Center at 1-800-800-5973.
- If the "Thermal runaway (disable)" message appears (as described later in this UMDC) on your **cobas** Liat analyzer running software version 3.3.0, stop testing on the analyzer and contact the Roche Support Network Customer Support Center at 1-800-800-5973.
- For handling previous positive results generated with the **cobas** SARS-CoV-2 & Influenza A/B test for use on the **cobas** Liat analyzer, follow your laboratory's standard operating procedures to investigate the potential for false positive results.
- Complete all sections of the enclosed faxback form (TP-01256) and fax it to 1-866-503-1216 or email it to roche6136@stericycle.com by April 8, 2021.
- File this Urgent Medical Device Correction (UMDC) for future reference.

over...

Roche Diagnostics Corporation

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