LAB Dept MEETING - Huddles

Date of Meeting: 12/19/2017

Attendees: Myrna Ocab, Priscila Dar, Tammy Rantung, Quang Trinh, Erick Galvey, Tessa Strickland, Letty Fajardo, Mark Gomez, Marietes Gonzalez, Elliott Faure, Melanie

Magee, Janet Gerges, Denise Topliff, Marissa Calilung

Topic	Details	Action Item, responsible person, date due, or informational only
SAFETY TIP	 Merry Christmas Everyone Thank you all for your hard work and commitment to patient care! 	Informational
	 Chemical Hygiene training (quiz + KP Learn certificate) was due yesterday, 12/18/17. KP Learn course - Chemical Hygiene Training for Lab Employees 2017-Course # 00747358. Submit to Marissa as soon as possible if you haven't done so. Chocolate Media QC- Forms used and instructions attached. Must be sent to Regional lab for QC for EVERY new shipment. Does not matter is it is the same lot number as previous. Must be accessioned before sending using the MR number provided on the form Check media expiration date before using. Discard if expired. It is not acceptable to use any expired product. Continue to log Blood Culture Media and save the QC document in the Microbiology Media Quality Control binder every time we open the box. Follow instructions in the binder. We added another schedule draft to be posted. The first 2 final schedules will be taken out at the same time to be replaced by 2 final ones both at the same time. New Gen Lab Policies and Procedures – read, acknowledge and initial- clip board on top of center table. 	ALL STAFF
	 C. diff 6 months competency is due by Friday, 12/22/17. Complete all daily Preventive Maintenance Logs before 2018 ends. Incomplete ones with post its- please take care of this. BB CLS please remember to change out the ALBQ at 7 days, and the 0.8% Selectogen and Affirmogen at 5 days. Beginning January, I will be keeping track and writing up incidence of non-compliance. 	CLS

	•	Reminder (from 7/20/17 huddle): Add morning labs to TC or STAT if ordered from 200-500 am. If order is a series e.g. Q4 and there will be another draw at 600 am, we will draw am TC/STAT at 200 am and draw morning labs at 6 am. H2 staff are required to help with am draws on weekends and holidays. H2 are also required to pick up samples from the floors during the week.	Phlebotomist
UBT		·	

This concludes the Minutes of the	_12/19/17	Lab Staff Meeting.
Prepared by:Nancy	Date:	_12/21/17



DEC 1 9 201.

PRODUCT ANNOUNCEMENT

by Marissa Caliluna

Clinical Chemistry Global Labeling and Packaging Update AU, UniCel DxC Synchron, and IMMAGE Product Lines

October 2017

Dear Beckman Coulter AU, UniCel DxC Synchron, and IMMAGE Customer,

Beckman Coulter would like to inform you that we are improving our product labeling and packaging. Over the next few months, you may notice changes to our product labeling as a result of this initiative. We are also updating our document and label formatting. There are no changes to our clinical chemistry products.

Some of the improvements include:

- > Symbols that replace product labeling text, harmonizing our global packaging.
- > Removal of the Globally Harmonized System of Classification and Labeling of Chemicals (GHS) hazardous statements and ingredients from our kit packaging. GHS pictogram(s), signal word, and hazard statement code(s) will be retained.
- > Removal of content volume from primary container labels.
- > For the AU product line, the Reagent Instructions for Use (IFU) Guide contains a comprehensive glossary of the symbols used in our packaging. For more details, refer to the AU Product Line information below.
- > For the Synchron two liter modular reagents, the bar codes and variable lot number, expiration date, and date of manufacture information will now reside on the left portion of the kit label and will no longer be present on a separate panel of the kit box.

AU Product Line

The Reagent IFU Guide contains a comprehensive list of all the symbols and definitions, English terms used in setting sheets with language specific translations, and disclaimers used in our packaging. The reference number of the general Reagent IFU Guide is "BAGuide" for US Markets and "BLGuide" for Outside US Markets. You can obtain the Reagent IFU Guide from the Beckman Coulter website, Technical Documents section using the link below.

https://www.beckmancoulter.com/wsrportal/page/techdocSearch

Select Search By Item/REF/Document Number, then enter the reference number and language you require.

> Item/REF/Document Number: BAGuide or BLGuide

Reviewed

DEC 1 9 2017

by Marissa Calilung M

For Beckman Coulter's worldwide office locations and phone numbers, please visit www.beckmancoulter.com/contact

- > Document Category: Consumable IFU/CIS/Setting Sheet
- > Language: language required

You now have the ability to download zipped files of all or selected reagent IFUs in pdf and Word format, from the *Technical Documents* section of the Beckman Coulter website. A step by step instruction document, *Instructions for Downloading AU Application Documents*, has been developed to guide you through the downloading technical documentation process. For detailed *Website* PAL, reference number C11460.

UniCel DxC and IMMAGE Product Lines

Each reagent IFU has been updated to comply with Beckman Coulter Global Labeling Policy. You can obtain reagent IFUs from the Beckman Coulter website, Technical Documents section using the link below.

https://www.beckmancoulter.com/wsrportal/page/techdocSearch

Please share this information with your laboratory staff and retain this notification as part of your laboratory documentation.

If you have any questions regarding this product, please contact Beckman Coulter Customer Support at 1-800-854-3633 from the United States and Canada, or your local Beckman Coulter Representative.

Thank you for your continued support of Beckman Coulter products and services.

Sincerely,

Lisa Hammett

Chemistry Product Management

Xisa Hammi

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SCPMG Laboratory System - Regional Reference Laboratories

CELIAC DISEASE PANEL - EMA INTERNALIZATION

The Regional Reference Laboratory System is pleased to announce effective **December 20, 2017**, the Immunology Department will internalize testing for the reflexed Endomysial IgA antibody (EMA) screen and titer component of the celiac disease panel. Previously, the reflexed EMA testing was sent to Quest Diagnostics. Other screening components of the celiac disease panel (i.e., tissue transglutaminase antibody, serum IgA) are already performed at RRL, and this will complete internalization of the celiac disease panel.

	TEST INFORMATION		
KPHC Name	PNL CELIAC DISEASE AMB SCAL (Ambulatory)		
KPHC Order Code	PNL CELIAC DISEASE IP SCAL (Inpatient)		
KRMS Procedure Code	Medical center specific		
KKIVIS PTOCEUUTE CODE	8278405, 8351605, 8351607, 8625507, 8625009		
	Screening Tests:		
	 Tissue Transglutaminase Antibody (tTg IgA) 		
	Serum IgA		
Tests included in celiac disease panel	Reflex Tests:		
	 Tissue Transglutaminase Antibody (tTG IgG) 		
	Endomysial Antibody Screen (EMA IgA)		
	 Endomysial Antibody Titer (EMA Titer IgA) 		
NEW for 12/20/17 - internalized tests	 Endomysial Antibody Screen (EMA IgA) 		
	Endomysial Antibody Titer (EMA Titer IgA)		
Reference Range - EMA	Negative		
Methodology - EMA	IFA		
Specimen (container), and minimum volume	2 x 5.0 mL serum (GLD6)		
	Minimum: 1 mL serum per tube		
Transport Requirements:	Refrigerated		
	Ambient: Not Applicable		
Specimen Stability:	Refrigerated: 7 days		
	Frozen: 3 weeks		
Testing Days	Monday-Friday		
Turnaround Time:	72 hours		

QUESTIONS?

Client Service Center: 1-888-4LAB NFO, or tie line 8-397-7077

JiYeon Kim, MD, MPH; Physician Director, Esoteric Chem & Immunology, Special Coag: 818-503-6710 or tie line 8-397-6710





Notice of Product Discontinuation (Part No. 3MA800) New Product Introduction (Part No. 133800)

To: Ms. Marissa Calilung
Email: marissa.g.calilung@kp.org

Date: December 18, 2017

Subject: Notice of Product Discontinuation (Part No. 3MA800) / New Product Introduction (Part No. 133800)

NEW PRODUCT INTRODUCTION

Micro-Sample Test Kit (Part Number 133800)

A new Micro-Sample Test Kit, part number 133800, will launch January 15, 2018 and replace Micro-Sample Test Kit part number 3MA800. The kit is for use with the Model 3320 Single-Sample Micro-Osmometer. The previous model, the Model 3300 Single-Sample Micro-Osmometer, was discontinued in 2005, and is no longer serviced or supported.



We have **conveniently packaged** chamber cleaners, sampler tips, and a plunger wire inside the new Micro-Sample Test Kit so that **everything you need to run a test is right at your fingertips**. Replacing the plunger wire on your 20µL Ease-Eject™ Sampler after every 500 tests or with each box of sampler tips **helps ensure optimal performance** of your instrument and **reduces time spent troubleshooting**.

PRODUCT DISCONTINUATION

Micro-Sample Test Kit (Part Number 3MA800)

The Micro-Sample Test Kit, part number 3MA800, will be discontinued as of January 15, 2018. The replacement consumable for 3MA800 is 133800. Prior to the end of the 2017, we will no longer honor orders for 3MA800 exceeding 10% of your previous order quantities.



Orders for the 3MA800 that come in after the discontinuation date will need to be modified to include the new 133800. To prevent any delays in shipping please ensure this communication is shared with the appropriate personnel at your facility.

Discontinued Product		Replacement Product	
Part Number	Description	Part Number	Description
3MA800	Micro-Sample Test Kit (Includes 500 sampler tips and 500 chamber cleaners)	133800	Micro-Sample Test Kit (Includes 500 sampler tips, 500 chamber cleaners, and 1 plunger wire

We thank you for choosing Advanced Instruments as your laboratory supplier. For more information about our products, please visit our website at www.aicompanies.com or http://www.aicompanies.com contact Advanced Instruments and your authorized distributor to learn more.

Instructions to accession media QC for SW

1. Go to Cerner Order entry

2. Enter the following Client: Non-Patient

Medical Record Number: ZZ000001783

Orderable: Environmental Culture Specimen type: Surveillance

Performing Location: MVH SrvArea

Ordering Physician: Dr. Taira

05/08/2015 PSJ

SCPMG Laboratory System Moreno Valley Medical Center Laboratory Microbiology Forms

Diagnostics (BBL) Media

California Division-South Medical Care Program Kaiser Permanente

Acceptable Yes or No? Checked? Defective media after initial check | Choc QC 9. excessive moisture or dehydration 11 presence of precipitates 10. obvious contamination (do not use/discard media) 5. insufficient again in the plates (<3mm) Initial 8. excessive bubbles or rough surfaces 6. hemolysis of blood containing agar tubes/plates per batch). Checked for defective media upon receipt (10 Acceptable? Yes or No 7. cracked or damaged plates Quantity (plates/ tubes) Expiration Lot number Check for the following upon receipt: 1. Change in expected color of media 2. agar detached from the plates 4. unequal filling of plates 3. frozen or melted agar Received No. Date 4 2 9 ∞

Lab Manager will review the Choc QC result in Cerner

Note: Send Chocolate Media to SW for Quality Control Testing. Follow laboratory protocol for sending plates to Regional Lab Cutoff for an acceptable failure rate detailed in CLSI M22-A3 is 0.5%

Manager Review:

Kaiser Permanente Moreno Valley Community Hospital CHOCOLATE AGAR QUALITY CONTROL MRN ZZ000001783

PLACE BARCODE HERE

(Environmental Worksheet)

Chocolate Agar QC			
Manufacturer: BBL	Exp. Date:	Date Si	ubmitted:
Lot #:	RESULTS		
Organism	Actual	Expected	Comment
Neisseria gonorrhoeae ATCC #43069		Growth	Johnson
Haemophilus influenzae ATCC #10211		Growth	

For S	herman Way Lab Use	Only
QC RESULTS:	Acceptable	Tech:
	Unacceptable	Date:

PROCEDURE

- 1. Send TWO (2) sterile, uninoculated Chocolate Agar plates to the Sherman Way Regional Lab with each new lot number or new shipment that you receive.
- 2. Accession the Chocolate Agar under the non-patient sample (Environmental) worksheet. This will ensure that you receive the QC results in a timely manner and eliminate the possibility of the completed form getting lost.
- 3. Record the following information: Lot #, Expiration Date and Date Submitted.
- 4. Please review all results in a timely fashion so unacceptable results can be acted upon
- 5. Use the computer hard copy for your QC records.
- 6. Results will be sent through inter-office mail if medium is received unaccessioned.



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SCPMG Laboratory System - Regional Reference Laboratories

HEMOGROBINA C METHODOLOGY JUDIOR

- The Regional Reference Laboratories (RRL) upgraded Hemoglobin A1c (A1c) instruments and reagents in early October 2017, from Roche Integra 800/Tina-Quant Gen 2 Reagents to Roche c513/Tina-Quant Gen 3 Reagents. A1c results are about 0.4% A1c lower than with the prior method; the new method is state of the art in A1c accuracy, and is a secondary reference method for the National Glycoprotein Standardization Program (NGSP).
- While >99% of patient results with the new method are reproducible, rarely, some results have been found to be unexpected from prior history. Additional quality assurance measures have been added, and unusual results are being investigated on a case-by-case basis. If you have any questions about an A1c result, consider re-testing the patient and referring the questionable result to the 24-7 RRL Client Services hotline at 818-503-7077 (tie line 8-397-7077), or via "DR ADVICE LABORATORY" referral in KP HealthConnect, where one of our Clinical Pathologists will be happy to provide you with detailed assistance. We will also be happy to retest the original sample if the request is received within 5 days of collection.

2.(0)

Q: I've seen a recent change in A1c for my patient larger than 0.4% A1c. What does this mean?

A: Several factors can affect A1c values. First, of course, is a true change in the patient's diabetes control. Red blood cell count changes may also affect A1c levels. However, if you remain concerned about a significant difference that is inconsistent with current clinical findings, please contact the laboratory at the number provided above.

Q: How should I manage my patient who was previously diagnosed with prediabetes or diabetes based upon A1c who now falls in the normal range?

A: Glycemic control is best assessed over time with several A1c results, as well as laboratory and/or home glucose monitoring results, if available. Recall that repeatedly elevated A1c values (>6.4% A1c) on at least two separate occasions are required to diagnose diabetes.

Q: Should I use A1c for screening my patient for diabetes?

A: While A1c is considered an acceptable method for screening for diabetes, a new diagnosis of diabetes or prediabetes is best supported by repeatedly abnormal A1c results, or by supporting evidence from fasting glucose or oral glucose tolerance tests. Glucose measurements may be preferred for type 1 diabetes and gestational diabetes; patients with anemia, hemoglobinopathies, chronic renal disease and other states that affect RBC lifespan; patients with HIV or pancreatitis; or with medications that disrupt glycemic control, e.g., corticosteroids, antipsychotics.

Q: What should I do if the A1c result is "Unable to Calculate"?

A: This result indicates either that the patient has profound anemia, a hemoglobinopathy, or a condition that affects red blood cell lifespan is present. Consider using glucose or fructosamine measurements instead.

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SCPMG RRL Client Services Center: 1-888-4LAB NFO, or tie line 8-397-7077

Darryl E. Palmer-Toy, MD, PhD - Physician Director, SCPMG RRL Core Laboratories

David Quam, MD - Assistant Executive Medical Director, SCPMG Regional Laboratory System

JiYeon Kim, MD, MPH - Physician Director, SCPMG RRL Esoteric Chem & Immunology, Special Coagulation, Lab Informatics

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



SCPMG Laboratory System - Regional Reference Laboratories

The Regional Reference Laboratory System is pleased to announce a new SmartGroup panel will be available on December 20, 2017 for antiphospholipid antibodies (aPL) testing, and will include orders for anticardiolipin antibodies, anti-beta-2-glycoprotein antibodies, and lupus anticoagulant.

Testing for aPL can be considered in patients with unusual venous or arterial clotting and/or pregnancy morbidity, to evaluate for antiphospholipid syndrome (APS). Positive tests for one or more aPL must be persistent and repeatable at least 12 weeks apart to meet laboratory criteria for antiphospholipid syndrome (APS). Please note that not every positive aPL result is clinically significant, and both clinical (thrombosis, pregnancy morbidity) and laboratory criteria must be present for the diagnosis of APS.

Patients who are on anticoagulant drugs can make interpretation of a prolonged aPTT and other clot-based screening tests for a lupus anticoagulant problematic; in contrast, immunoassays for anticardiolipin and anti-beta-2-glycoprotein antibodies are not affected by concurrent use of anticoagulant medication.

TEST NEGRINATION

SMARTGROUP PANEL NAME(S):

- PNL ANTIPHOSPHOLIPID ANTIBODY SYNDROME (APS) SCREEN AMB SCAL
- PNL ANTIPHOSPHOLIPID ANTIBODY SYNDROME (APS) SCREEN IP SCAL

KPHC TESTS [EAPS] IN APS SMARTGROUP PANEL:

- LUPUS ANTICOAGULANT PANEL [250719]
- CARDIOLIPIN IGG AND IGM [206475]
- BETA 2 GLYCOPROTEIN I IGG, IGM, IGA [200973]

(0) 1 1 1 1 0 1 LT

Client Service Center: 1-888-4LAB NFO, or tie line 8-397-7077

JiYeon Kim, MD, MPH; Physician Director, Esoteric Chem & Immunology, Special Coag: 818-503-6710 or tie line 8-397-6710

SCPMG Laboratory System - Regional Reference Laboratories

TOXOPLASMA IGM TESTING - CHANGE TO UNIT OF MEASURE, DECIMAL PLACES

Effective December 12th, 2017 the SCPMG Regional Reference Laboratory Care Delivery System will switch from the miniVIDAS to the VIDAS 3 testing platform for detection of *Toxoplasma* IgM antibodies in serum. Concurrent with this change, though the interpretive ranges for *Toxoplasma* IgM results will remain the same, the new instrumentation will not report a unit of measure. Formerly, the unit of measure for results was reported as a Relative Fluorescence Value (RFV).

Additionally, Toxoplasma IgM results will now be reported with 2 decimal places (formerly 3).

QUESTIONS?

Client Service Center, 1-888-4LAB NFO, or tie line 8-397-7077

Jonathan Craig Gullett, MD, Physician Director of Microbiology, 909-703-6033, or tie line 263

Ken Van Horn, PhD, D(ABMM), Technical Director of Microbiology, 909-703-6062, or tie line 263