LAB Dept MEETING – Huddles

Date of Meeting: August 28,2019
Attendees: Jocelyn Ybarra, Juliet Garlejo, Quang Trinh, Rizza Alcordo, Alejandro Tolentino, Jacob Morgan, Tessa Strickland, Greg Johnson, Bill Craig, Michelle Trammell, Mark Gomez, Juanita Fernandez, Vanessa Cardenas, Patricia Chea, Marissa Calilung, Marie Rutledge, Theda Bryant

Topic	Details	Action Item, responsible person, date due, or informational only
KUDOS	• From Vanessa …Thank you to all lab staff who helps in processing, answering the phone, etc. when no one is at the front in processing area. • Thank you to all CLS trainers for your patience and willingness to share your knowledge and experience to new employees	Informational
SAFETY TIP	• Safety- A courier almost trip on a chair in processing area. Consensus: Have couriers (Quest) use the side door instead of the processing door.	Informational
TB exposure	• If you receive a call asking about TB exposure, please get their information and tell them that you will give this to your manager, and we will call them back.	ALL STAFF
ENGIE waste quiz	• Please complete the quiz and submit to Tricia. • We will give the answer after everybody has submitted their quiz	ALL STAFF
Chemistry Bio-Rad QC Materials	• Always follow the manufacturer's instructions in thawing QC materials. Below is the proper way of thawing Liquichek™ Unassayed Chemistry control Levels1 and 2: **To thaw the product, allow it to stand at room temperature (18 to 25°C) until completely thawed but no longer than one (1) hour. For optimal analyte stability in the thawed state, promptly return to 2 to 8°C storage after each use. *** Do not let ALL frozen QC vials thaw in refrigerator! Follow instructions step by step.** **Thawed Opened:** Before each use, gently swirl the contents until homogeneous with no visible signs of precipitate. For optimal stability of the product in the Thawed Opened	CLS

	stability claim duration, minimize the time at room temperature to no more than 20 minutes daily. If performing trace metal analysis, do not mix by inversion. Promptly replace the stopper and return the product to 2 to 8°C storage after each use. • For all other QC thawing or handling instructions, refer to binder- Bio-Rad QC Package Inserts. It's very important to follow manufacturer's instructions for optimal performance.	

This concludes the Minutes of the __8/28/2019_____ Lab Staff Meeting.

Prepared by: _Lab Management_ Date: ___August 28, 2019_____

August 15, 2019

URGENT MEDICAL DEVICE RECALL

Enzymatic Creatinine Reagent (CR-E 2 x 200)
Triglycerides GPO Blanked Reagent (TG-B 2 x 300)
Uric Acid Reagent (URIC 2 x 300)
Direct Bilirubin Reagent (DBIL 2 x 200; DBIL 2 x 300)
Total Bilirubin Reagent (TBIL 2 x 300, TBIL 2 x 400)

REF	LOT	
A60298	All	All
445850	All	All
442785	All	All
439715 and 476856	All	All
442745 and 476861	All	All

Attention Beckman Coulter Customer,

Beckman Coulter is initiating a field action for the products listed above. This letter contains important information that needs your immediate attention.

ISSUE:	Beckman Coulter has identified that N-acetyl p benzoquinone imine (NAPQI), a metabolite of acetaminophen (paracetamol), may cause negative interference for the following assays if present in high quantities in serum due to acetaminophen overdose: • Enzymatic Creatinine (PN A60298) • Triglycerides GPO Blanked (PN 445850) • Uric Acid (PN 442785) • Direct Bilirubin (PNs 439715 and 476856) • Total Bilirubin (PNs 442745 and 476861)
IMPACT:	• NAPQI, in toxic concentrations, may potentially lead to erroneously low results for Enzymatic Creatinine, Triglycerides GPO Blanked, Uric Acid, Direct Bilirubin, and Total Bilirubin. The risk to patient safety of this event has been determined as remote for Enzymatic Creatinine, Direct Bilirubin, and Total Bilirubin and highly unlikely for Triglycerides GPO Blanked, Uric Acid, Direct Bilirubin, and Total Bilirubin. • Acetaminophen does not interfere with the assays.
ACTION:	No action is required by your laboratory. However, laboratories should be aware that there is a remote probability that NAPQI, in toxic concentrations, may potentially lead to erroneously low results for Enzymatic Creatinine, Triglycerides GPO Blanked, Uric Acid, Direct Bilirubin, and Total Bilirubin.
RESOLUTION:	The following statement will be added to the Interfering Substances section of the Enzymatic Creatinine, Triglycerides GPO Blanked, Uric Acid, Direct Bilirubin, and Total Bilirubin Chemistry Information Sheets (CIS):

	"N-acetyl-p-benzoquinone imine (NAPQI), a metabolite of acetaminophen (paracetamol), may generate erroneously low results in samples for patients that have taken toxic doses of acetaminophen (paracetamol)."

Please share this information with your laboratory staff and retain this notification as part of your laboratory Quality System documentation. If you have forwarded any of the affected product(s) listed above to another laboratory, please provide them a copy of this letter.

So that we are assured you have received this important communication, please respond within 10 days in one of the following ways:

- Electronically, if you received this communication via email.
- Manually, complete and return the enclosed Response Form.

If you have any questions regarding this notice, please contact our Customer Support Center;

- From our website: http://www.beckmancoulter.com
- By phone: call 1-800-854-3633 in the United States and Canada.
- Outside the United States and Canada, contact your local Beckman Coulter representative.

We apologize for the inconvenience that this caused your laboratory.

Sincerely,

David Davis
Senior Director, Regulatory Affairs

Enclosure:
Response Form