QuidelOrtho™

April 2023

URGENT PRODUCT CORRECTION NOTIFICATION

Potential Bias Observed in VITROS Chemistry Products HbA1c Reagent Kit

Dear Valued Customer,

This notification is to inform you that Ortho Clinical Diagnostics (Ortho) has confirmed an issue with VITROS Chemistry Products HbA1c Reagent Kit where affected reagent packs:

1. may generate biased results (compared to unaffected packs) and
2. have the potential to exhibit atypical drift after loading on the system

Product Name	Product Code (Unique Device Identifier)	Affected Lot	Expiry
VITROS Chemistry Products HbA1c Reagent Kit	6842905 (10758750030729)	29-9396	2023-SEP-02
		29-9466	2023-SEP-02
		30-9647	2023-NOV-25
		30-9803	2023-NOV-25
		31-9648	2024-JAN-24
		32-9925	2024-APR-14
		33-1097	2024-JUL-18
		33-1105	2024-JUL-18
		33-1228	2024-JUL-18
		34-1345*	2024-OCT-17

Issue Description

During Ortho's release testing of Lot 34-1345, an issue was found that up to 6% of reagent packs may generate biased results. Subsequent testing also confirmed atypical drift on results obtained from affected reagent packs. As the issues were detected in the most recent lot, Ortho's investigation is on-going.

*Release testing performed on reagent Lot 34-1345 identified this issue. In an abundance of caution, the required actions are applicable to all lots within expiry (listed above) as well as all future lots until your laboratory receives an additional notification from Ortho. However, while data is limited, a review of the release testing indicated no other lots were impacted.

Important notes:

- This issue is detectable by performing Quality Control (QC) by following the Required Actions instructions below.
- Pack-to-pack variability or within pack drift on affected reagent packs may cause unexpected positive bias (drift) or negatively-biased (pack-to-pack variability) results.
- If an affected pack is used for calibration, the QC results obtained post-calibration from the same pack may be within your laboratory's established range. It may take up to 2 days after loading to detect the unexpected drift of QC results obtained from the same affected reagent pack.
- If calibrating on an unaffected pack, any subsequently affected packs will show a negative bias that drifts positive over time on the system.

Impact to Results

The estimated impact to results for both the reagent pack-to-pack bias and atypical drift are provided below. Your laboratory's results may differ due to pack-to-pack and other sources of variability.

The following table represents the magnitude of bias (QC or patient samples) observed between a result obtained from affected and unaffected pack.

Fluid	% A1c			mmol/mol		
	Unaffected Pack Result	Affected Pack Average Result Bias	Affected Pack Maximum Result Bias	Unaffected Pack Result	Affected Pack Average Result Bias	Affected Pack Maximum Result Bias
A1c PV I	5.39	-0.63	-0.80	35.4	-6.8	-8.7
A1c PV II	9.64	-1.65	-2.07	81.8	-18.1	-22.6

The following table represents the magnitude of observed within-pack drift between time = 0 hours (defined as time loaded on the system), 8 hours, and 24 hours after loading the affected reagent pack.

Affected Pack (%A1c)						
Fluid	Initial Result Time =0	Average Result Bias After 8 Hours	Maximum Result Bias After 8 Hours	Average Result Bias After 24 hours	Maximum Result Bias after 24 hours	2x Within-Lab SD
A1c PV I	4.83	0.11	0.16	0.32	0.48	0.30
A1c PV II	8.06	0.28	0.41	0.83	1.24	0.48
Affected Pack (mmol/mol)						
Fluid	Initial Result Time =0	Average Result Bias After 8 Hours	Maximum Result Bias After 8 Hours	Average Result Bias After 24 hours	Maximum Result Bias after 24 hours	2x Within-Lab SD
A1c PV I	29.2	1.2	1.7	3.5	5.2	3.30
A1c PV II	64.6	3.0	4.5	9.1	13.6	5.30

The results from any diagnostic test should be evaluated in conjunction with a patient's history, risk factors, clinical presentations, signs, and symptoms as well as the results of other tests.

The observed biases may potentially cause diagnostic confusion or misrepresentation of the effectiveness of treatment.

If QC fails, follow your laboratory's standard troubleshooting and assess results obtained since the last acceptable QC results. Discuss any concerns regarding previously reported results with your Medical Director to determine if action is needed.

Required Actions Instructions

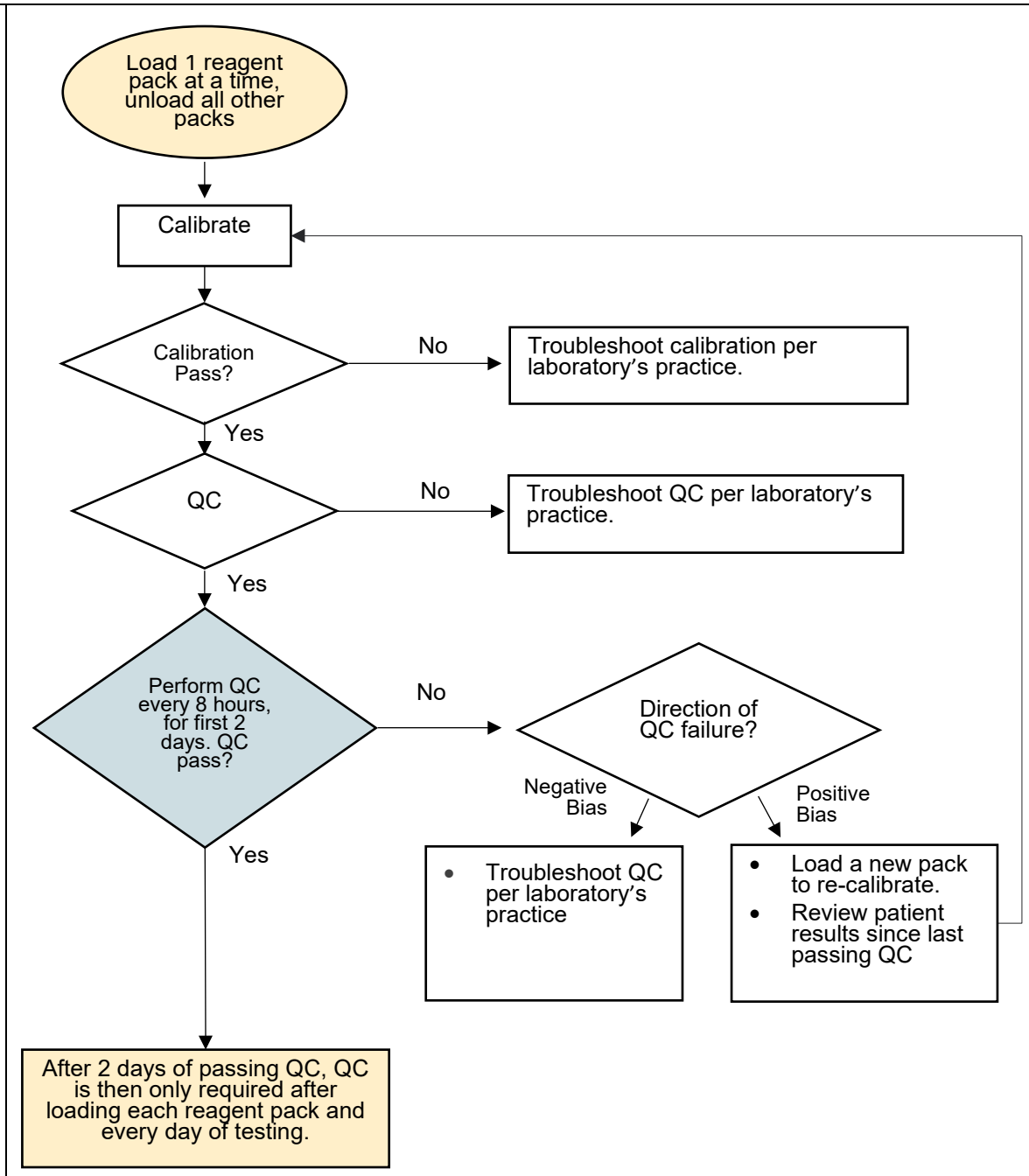
The following sequential instructions apply to all lots listed above and all future lots until further notice.

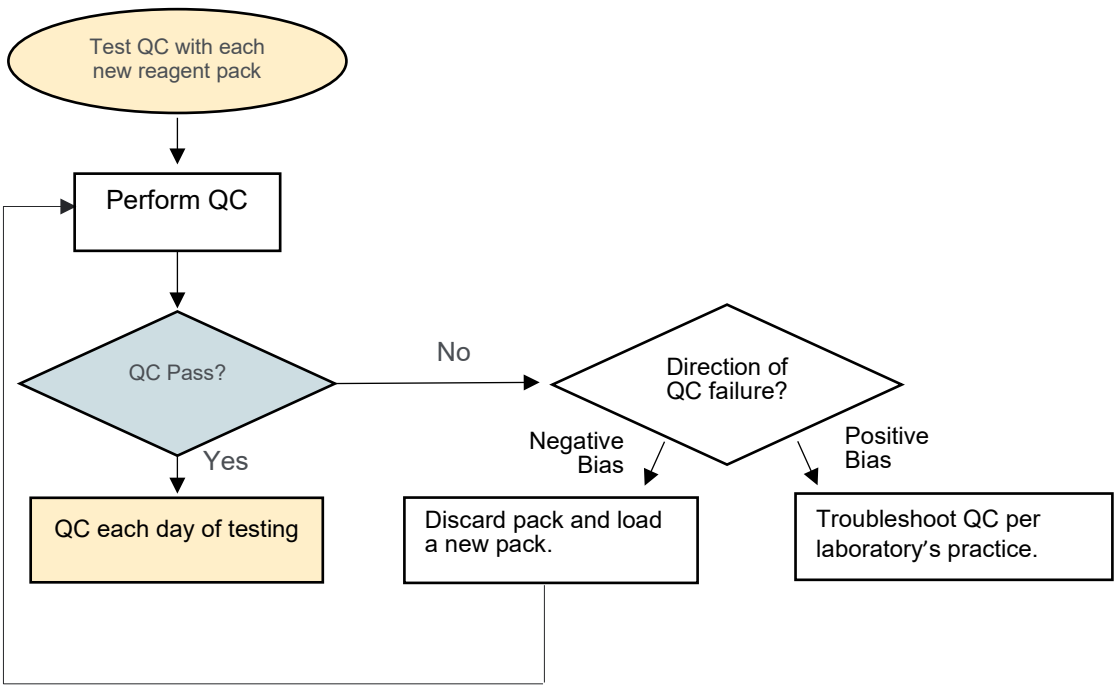
- **Reagent Pack Used for Calibration**
  - If your system currently has multiple HbA1c reagent packs loaded, leave one reagent pack on the system and unload all other reagent packs and store at 2-8 ºC (36-46 ºF) until needed.
  - Calibrate the one remaining HbA1c reagent pack on your system.
  - Perform QC after calibration. QC must be acceptable and subsequently performed **every 8 hours** of testing, for the **first 2 days** that the reagent pack is onboard the system.
  - If QC fails with a negative bias, troubleshoot according to your laboratory's procedure.
  - If QC fails with a positive bias, load a new pack and re-calibrate following the required actions. Review the patient results since the last passing QC.
  - After 2 days of QC passing within your laboratory's established QC range, performing QC every 8 hours is no longer necessary on that pack. Refer to Testing section below for QC requirements after calibration.

- **Reagent Pack Loading** – Only have <u>one</u> reagent pack loaded on your VITROS System.

- **Reagent Pack Used for Testing**
  - Once the reagent pack used for calibration is emptied, QC must be performed after loading *each* reagent pack and must be within the laboratory's established QC range prior to patient testing.
  - If the QC results are outside your laboratory's established range with a negative bias, then discard that reagent pack and load a new pack to perform QC again.
  - Ortho's data does not demonstrate an initial positive bias on affected reagent packs. If observed, follow your normal troubleshooting protocol.

Reagent Pack Used for Calibration



Reagent Pack Used for Testing	

Resolution

Ortho's investigation is on-going. A notification will be issued once additional information is available and/or the required actions described in this communication are no longer needed.

REQUIRED ACTIONS

- In an abundance of caution, follow the Required Actions Instructions listed above for all lots of VITROS HbA1c Reagent packs in your laboratory.
- Ortho will credit your account for affected VITROS HbA1c Reagent tests that have been discarded. Indicate quantities to be credited on the enclosed Confirmation of Receipt form.
- Complete the enclosed Confirmation of Receipt form no later than **2 May 2023**.
- Please forward this notification if the affected product was distributed outside of your facility.
- Save this notification with your user documentation or post this notification by each VITROS 5,1 FS/4600/5600/XT 7600 System until further notice.
- If your laboratory has experienced this issue and you have not already done so, please report the occurrence to your local QuidelOrtho representative or our Ortho Care™ Technical Solutions Centre.

Contact Information

We apologize for the inconvenience this will cause your laboratory. If you have further questions, please contact your local QuidelOrtho representative or our Ortho Care™ Technical Solutions Centre.

Sincerely,

Kevin Davies
Regional Product Support Manager (ASEAN & Korea)

Ortho Clinical Diagnostics (Ortho), a wholly owned subsidiary of QuidelOrtho Corporation, is excited to share our new logo and brand with you. Due to legal and regulatory requirements for diagnostic products, you may continue to see the names and brands of Quidel and Ortho in addition to QuidelOrtho on our packaging, contracts, and marketing materials.

Questions & Answers

1. **What is the likelihood that I will receive an affected pack?**

   The occurrence rate of an affected pack is up to 6% in Lot 34-1345.

2. **Will QC detect if I have an affected reagent pack? When should QC be performed? What should I do if the QC fails?**

   Yes, QC will detect an affected reagent pack after loading and performing QC.

   If the affected reagent pack is used for calibration, the QC may not detect the bias initially after loading. Thus, QC should be performed after calibration and every 8 hours of testing for the first 2 days.

   Refer to the Required Actions Instructions above if the QC fails with reagent packs used for calibration and testing.

3. **Why do I need to run QC samples every 8 hours of testing for the first 2 days for the reagent pack I calibrate on?**

   After calibration on an affected pack, QC results may initially produce acceptable results. An affected pack may also exhibit atypical drift which would cause results, including QC, to then drift out of the acceptable range. If an affected pack is used for the calibration, QC will detect the atypical drift within the first 2 days after loading. In an abundance of caution, QC should be performed after calibration and every 8 hours of testing for the first 2 days.

4. **If I am on a previous lot, do I need to re-calibrate?**

   Yes, you must re-calibrate with your current lot or new lot. Refer to the Required Actions Instructions for reagent packs used for calibration.

5. **Can patient samples be tested with the reagent pack that I have calibrated on?**

   Yes, as long as the instructions in this communication are followed, the reagent pack can be used for patient testing due to the low probability of the occurrence rate up to 6% of reagent packs.

6. **Will I receive a replacement for the reagent that my laboratory discards?**

   No, due to the limited supplies, only credit will be applied to your account.