
Product Notification

Dear Valued Customer:

PRODUCT: MULTIGENT Hemoglobin A1c Reagent

CATALOG NO.: 02K96-20

LOT NO.: All lots within expiry date

Please review the information carefully for changes to the handling of pre-treated samples (hemolysates) and follow the necessary actions.

INTENDED USE:

The MULTIGENT HbA1c assay is used in clinical laboratories for the quantitative in vitro measurement of percent HbA1c (HbA1c fraction) in human whole blood on the ARCHITECT cSystems and the AEROSET System. The HbA1c assay is intended to aid in the monitoring of long-term blood glucose control and compliance in individuals with diabetes mellitus. The MULTIGENT HbA1c assay is not intended for use in diagnosing diabetes mellitus.

REASON:

Whole blood samples (either fresh or frozen) for HbA1c testing are pre-treated with MULTIGENT Hemoglobin Denaturant. The pre-treated samples are placed on the ARCHITECT cSystems and tested for glycated hemoglobin (HbA1c) and Total Hemoglobin (THb) concentrations. According to the package insert, pre-treated samples must be allowed to incubate for a minimum of 5 minutes at 15 to 30 °C prior to testing. Pre-treated samples are stated to be stable for "up to 8 hours at 15 to 30 °C and up to 48 hours if stored at 2 to 8 °C". However, recent studies have demonstrated that HbA1c measurements increase with time after the samples are pre-treated. Therefore, it is necessary to change the handling instructions for pre-treating samples for the MULTIGENT HbA1c assay. The investigation to determine root cause is ongoing.

There is no impact to any other HbA1c assay claims.

RESULT IMPACT:

Patient Samples

Patient samples show a rise in measured HbA1c with time after pre-treatment with Hemoglobin Denaturant. The magnitude of the rise is sensitive to temperature. Lower storage temperature markedly slows the rise in measured HbA1c and improves the accuracy of testing. The magnitude of the rise in measured HbA1c with time after pre-treatment is proportional to the HbA1c level so that higher levels are more affected.

Quality Control

Lyophilized Quality Control samples (Hemoglobin A1c Controls, List Number 2K96) show little or no shift with temperature and time after sample pre-treatment.

Calibrators

Calibrator samples (Hemoglobin A1c Calibrators, List Number 2K96) are not impacted.

The representative data in the Tables below demonstrates the performance expected for a range of HbA1c values.

IFCC Traceable Results

Samples	Target, mmol/mol	Initial Measurement (processed within 5-15 min)	1 Hour Measurement	% Change vs. Initial	17 Hour Measurement	% Change vs. Initial
Control 1	31.0	30.7	31.5	2.6	31.5	2.6
Control 2	101.0	102.5	103.1	0.6	105.0	2.4
Sample 1	31.8	29.8	31.9	7.0	32.3	8.4
Sample 2	65.3	63.9	67.3	5.3	69.2	8.3
Sample 3	97.5	99.4	104.7	5.3	107.4	8.0

NGSP Traceable Results

Samples	Target, HbA1c %	Initial Measurement (processed within 5-15 min)	1 Hour Measurement	% Change vs. Initial	17 Hour Measurement	% Change vs. Initial
Control 1	5.0	4.96	5.03	1.6	5.04	1.6
Control 2	11.4	11.53	11.58	0.5	11.76	2.0
Sample 1	5.06	4.87	5.07	3.9	5.11	4.8
Sample 2	7.81	8.00	8.31	3.9	8.48	6.0
Sample 3	10.78	11.24	11.73	4.3	11.97	6.5

ACTION REQUIRED:

Changes to the Handling of Pre-treated Samples:

1. Using a calibrated micropipette, dispense 400 μ L Hemoglobin Denaturant into a tube or appropriate sample cup.
2. Using another calibrated micropipette, withdraw 10 μ L of the well-mixed whole blood patient specimen or control.
3. Insert the pipette into the tube or appropriate sample cup containing the Hemoglobin Denaturant allowing the tip of the pipette to just make contact with the surface of the denaturant and accurately dispense 10 μ L of the sample (1:41 dilution).
4. Thoroughly rinse the pipette by withdrawing and re-dispensing the mixture twice always keeping the tip of the pipette in contact with the fluid in the tube.
5. Mix immediately by gently vortexing at medium speed for 5 to 10 seconds. Avoid foaming.
6. Allow the hemolysate to incubate for a minimum of 5 minutes at 15 to 30 °C prior to testing.
7. **Transfer the hemolysate to a tube or appropriate sample cup and place on the instrument between 5 to 15 minutes of making the hemolysate. NOTE: Hemolysate must be loaded in the priority bay or sample carousel for priority processing immediately.**
8. **Alternatively, the hemolysate may be immediately stored on ice for up to 2 hours if analysis will be delayed. NOTE: Hemolysate must be loaded in the priority bay or sample carousel for priority processing immediately.**
9. If testing is delayed beyond 2 hours, prepare fresh hemolysates.

Note: During storage, certain hemolysates have a tendency to settle. It is good laboratory practice to mix/swirl specimens prior to transferring them to the sample cup.

The HbA1c reagent package insert will be revised.

The representative data in the Tables below demonstrates the performance expected when using the changes to the handling of pre-treated samples. Data in the tables was obtained from pre-treated samples held on wet ice. Pre-treated samples at room temperature will give comparable results if tested between 5 and 15 minutes of preparation. Accuracy Pools have values that are traceable to IFCC and NGSP values. Whole blood samples were collected in plastic EDTA blood draw tubes and held at 2 to 8 °C until testing. All samples were less than 2 weeks old at the time of analysis.

IFCC Traceable Results

Samples	Target, mmol/mol	Initial Measurement	1 Hour Measurement	% Change vs. Initial	2 Hour Measurement	% Change vs. Initial
Accuracy Pool 1	31.8	29.8	30.2	1.4	30.3	2.0
Accuracy Pool 2	42.7	40.8	41.2	1.0	41.4	1.4
Accuracy Pool 3	75.1	71.5	73.9	3.3	74.7	4.4
Accuracy Pool 4	114.1	114.5	116.1	1.4	117.8	2.9
Blood Sample 1	35.9	36.0	36.6	1.6	37.4	3.8
Blood Sample 2	59.5	59.1	61.6	4.1	62.0	4.9
Blood Sample 3	67.9	67.8	68.9	1.7	69.4	2.4
Blood Sample 4	84.8	84.8	86.9	2.5	87.3	2.9

NGSP Traceable Results

Samples	Target, HbA1c %	Initial Measurement	1 Hour Measurement	% Change vs. Initial	2 Hour Measurement	% Change vs. Initial
Accuracy Pool 1	5.06	5.01	5.03	0.5	5.09	1.6
Accuracy Pool 2	6.06	6.02	6.08	1.1	6.17	2.4
Accuracy Pool 3	9.02	8.78	9.19	4.7	9.06	3.1
Accuracy Pool 4	12.59	12.66	12.92	2.0	13.03	2.9
Blood Sample 1	5.51	5.49	5.56	1.4	5.64	2.7
Blood Sample 2	7.62	7.61	7.87	3.4	7.95	4.4
Blood Sample 3	8.55	8.57	8.63	0.7	8.74	1.9
Blood Sample 4	10.10	10.10	10.31	2.1	10.36	2.6

ADDITIONAL ACTIONS:

- Make changes to your laboratory procedures for performing MULTIGENT HbA1c testing to implement the updated handling of pre-treated samples.
- Retain a copy of this letter for your laboratory records.
- If you have forwarded MULTIGENT HbA1c Reagents to another laboratory please provide a copy of this letter to them.

CONTACTS:

If you have any questions regarding this information, please contact Abbott Customer Service for U.S. customers at 1-877-4ABBOTT. Customers outside the U.S. should contact your local customer service.

Sincerely,

Thermo Fisher Scientific Inc
Technical Support Department