Evaluation of a New Metering Algorithm to Enable Whole Blood Sampling for VITROS® Chemistry Products A1c Slides* on the Ortho VITROS® 5600/XT 7600 Integrated and VITROS® 4600/XT 3400 Chemistry Systems

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Introduction

VITROS® Chemistry Products A1c Slides* are being developed for the measurement of glycated hemoglobin A1c on the VITROS® 5600/XT 7600 Integrated and VITROS® 4600/XT 3400 Chemistry Systems.

Fully suspended whole blood samples are required to enable accurate glycohemoglobin A1c testing on automated, routine clinical chemistry instruments. This can complicate the lab's workflow, resulting in users batch testing a limited number of samples together to ensure the red blood cells have not settled.

A new metering algorithm as a part of VITROS® INTELLICHECK® technology enables whole blood sampling and confirms that adequate red cells are sampled to the VITROS® A1c Slides* directly from a standard EDTA collection tube without any pre-treatment steps.

The following factors can affect the efficacy of the metering algorithm to resuspend whole samples:

- Sample volume within a collection tube
- Dimension of the collection tube
- Inherent qualities of the sample such as erythrocyte sedimentation rate (ESR)
- Hemoglobin concentration

Methods

The efficacy of whole blood sample resuspension was assessed by computing the percent bias/difference between the VITROS® A1c Slides measurement for samples up to 20 minutes of settling and for fully suspended samples (zero minutes settling) out of a standard 4 mL EDTA collection tube.

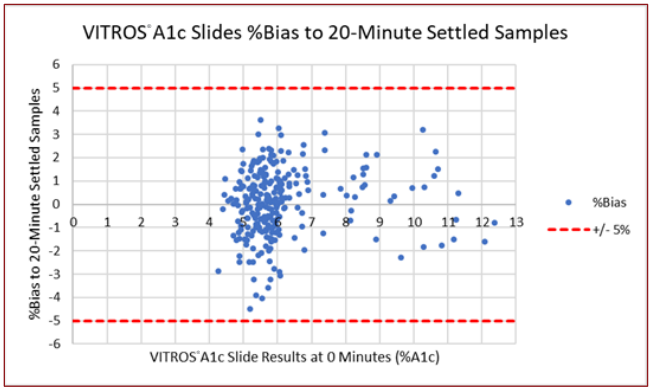
130 unique patient samples were cumulatively tested on four VITROS® Systems (VITROS® 5600/XT 7600 Integrated and VITROS® 4600/XT 3400 Chemistry Systems). Samples included local draws, sourcing from various vendors, and pre-screened high ESR samples.

Samples tested had hemoglobin concentrations between 8 and 17g/dL and %A1c values between 4 and 11%.

A sample is considered "passing" if the bias of the partially settled sample's %A1c measurement is within ± 5% of the suspended sample's %A1c measurement.

Results

100% (130 samples) of sample biases were within ± 5% for the 20-minute partially settled samples in EDTA collection tubes compared to the fully suspended samples for all VITROS® Systems tested. The results are shown in the plot below.



Conclusions

The data presented here demonstrates that the new metering algorithm enables whole blood sampling for VITROS® A1c Slides* could enable testing on the VITROS® Integrated and Chemistry Systems and is effective for at least 20 minutes sampled out of an EDTA collection tube or sample cup.

This feature combined with the use of VITROS® A1c Slides* on automated routine VITROS® Systems significantly could enhance the ease of use for the measurement of glycated hemoglobin A1c and improves the lab's workflow by enabling random access could improve testing (not batched) with an extended walkaway time up to 20 minutes.

*Not regulatory approved/cleared product, not available for sale. *The performance characteristics of this product have not been established.*

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Appendix – SI Units (mmol/mol)

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