

Qualification of a Veterinary Glucometer for Use in Yucatan Miniature Swine

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Introduction

- Over 537 million adults are living with diabetes mellitus, a number expected to rise to 643 million by 2030 and 783 million by 2045.
- Miniature Swine (MS) are commonly used for diabetic research. Typically, diabetes in MS is induced either chemically or surgically.
- The gold standard for determining blood glucose (BG) levels is with plasma using automated analyzers; however, it is crucial to have real-time BG monitoring via handheld point-of-care glucometers to make diagnostic decisions and capture information for research purposes.
- Glucometers are beneficial due to the small amount of blood required and the fast results.
- Human & veterinary glucometers are available commercially; however, none have been marketed with calibrations for use in swine. The model in use historically at our facility had been discontinued, and a new model was needed.
- The goal was to identify a glucometer to accurately capture real-time BG measurements in diabetic and non-diabetic Yucatan swine.

Method

- A preliminary trial was conducted to determine the suitability of glucometers before qualifying a glucometer for GLP use.
- Before blood collection, animals were withheld AM feed and insulin.
- 3 ml of blood was collected from each MS via previously implanted vascular access ports (VAP).
- Whole blood was immediately analyzed in duplicate using each glucometer.
- Remaining blood was processed, and serum was analyzed using an AU480® chemistry analyzer.

Preliminary Trial

- Male Yucatan Miniature Swine (n=7)
 - Non-diabetic (n=3)
 - Alloxan induced diabetic (n=4)
- Glucometers tested (**Figure 1**)
 - A veterinary glucometer (cat and dog codes) and a human glucometer were compared to the historically used veterinary glucometer and a chemistry analyzer.

Qualification Trial

- Male Yucatan Miniature Swine (n=12)
 - Non-diabetic (n=6)
 - Alloxan induced diabetic (n=6)
- Glucometers tested
 - A veterinary glucometer and a chemistry analyzer were compared to the historically used veterinary glucometer.
- International Organization for Standardization (ISO) performance standards were used to evaluate the glucometer's accuracy and qualify it for use.
 - BG < 100 mg/dL—95% of measurements within +/- 15 mg/dL
 - BG > 100 mg/dL—95% of measurements within +/- 15% mg/dL



Figure 1. Glucometers evaluated in Preliminary Trial. 1A) AlphaTrak 2 – Veterinary glucometer historically used at our facility but commercially discontinued. 1B) FreeStyle Lite – a human glucometer. 1C) AlphaTrak 3 – Veterinary glucometer marketed for dogs & cats. Both codes were evaluated.

Results

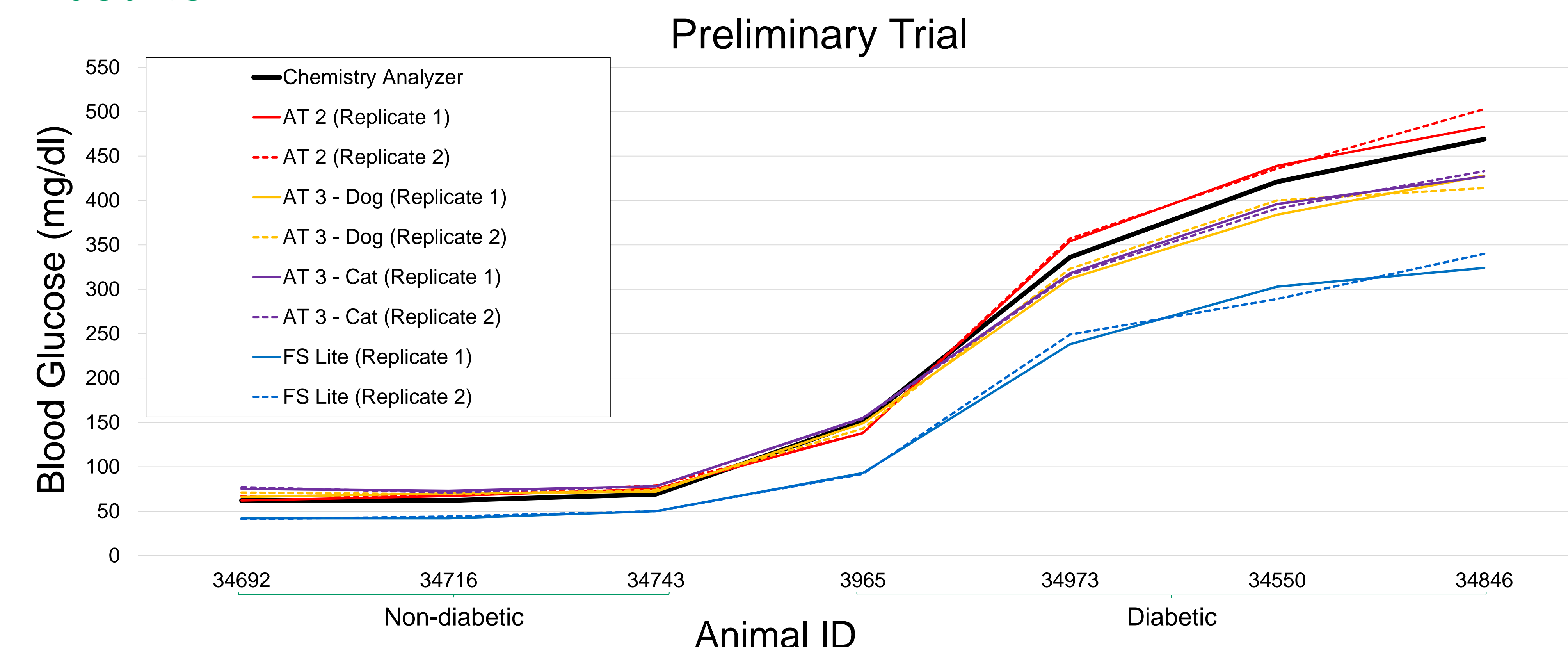


Figure 2. Preliminary Trial Results. AT = AlphaTrak (veterinary glucometer), FS = FreeStyle (human glucometer). Veterinary models outperformed the human glucometer. The dog code on the AT 3 was selected for the qualification trial, as it tended to pass control checks more frequently than the cat code and appeared it would fulfill ISO standards.

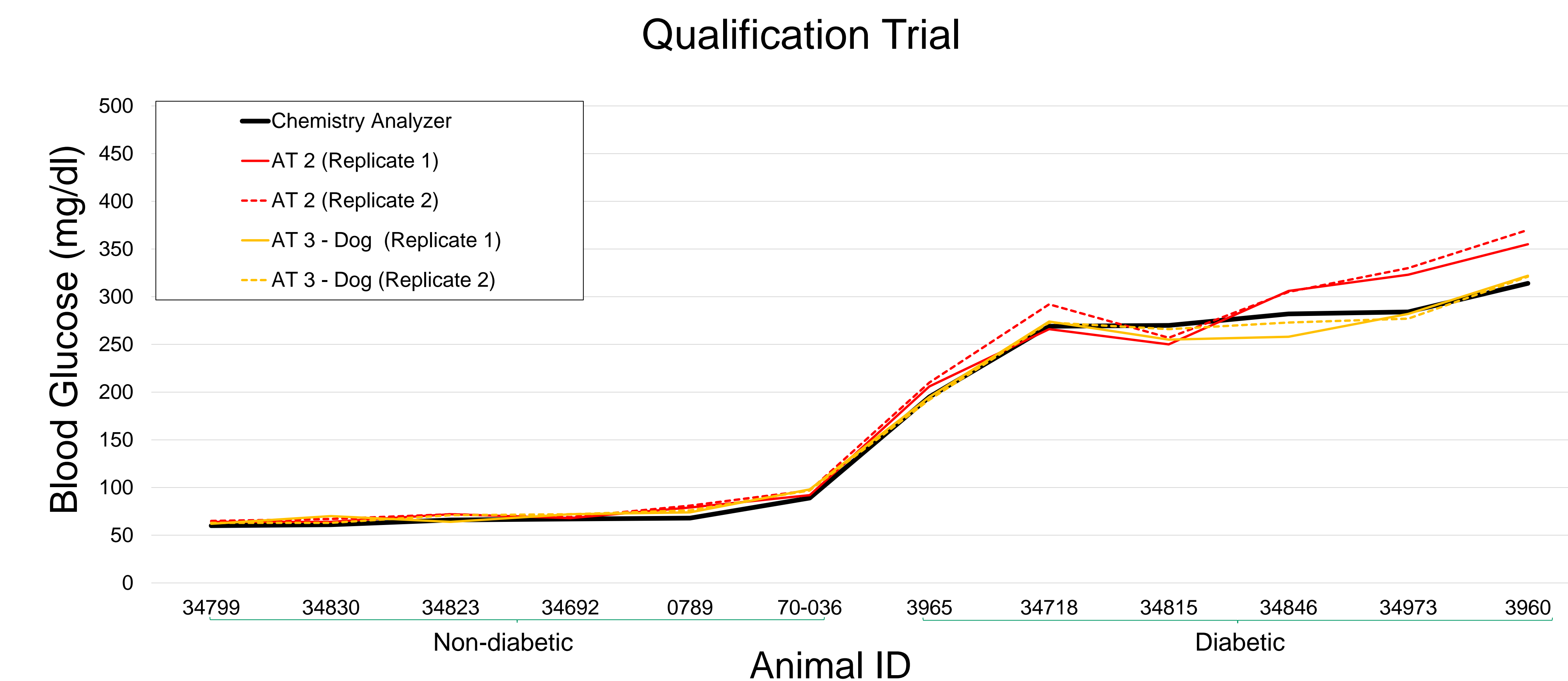


Figure 3. Qualification Trial Results. AT = AlphaTrak (veterinary glucometer). The AlphaTrak 3 met all ISO performance standard criteria. The AlphaTrak 2 failed to meet performance standards. The second replicates using the AlphaTrak 2 for animals 34973 and 3960 were over 15% mg/dl when compared to the chemistry analyzer.

Conclusions

- Preliminary trials indicated the AlphaTrak 3 (veterinary glucometer) provided superior results compared to the FreeStyle light (human glucometer).
- The AlphaTrak 3 (dog code) provides reliable results when comparing the BG values with the chemistry analyzer.
- For the qualification trial, all values from the AlphaTrak 3 fell within ISO performance standards, qualifying this glucometer for use in Yucatan MS.