Evaluation of the FreeStyle Precision Neo Blood Glucose Monitoring System

Objectives: To evaluate the performance of the Abbott Diabetes Care FreeStyle Precision Neo blood glucose monitoring system against the performance requirements for blood glucose monitoring in ISO 15197 in clinical and laboratory studies.

Methods: Accuracy and user performance in testing fresh capillary whole blood samples were assessed at two diabetes clinics. Results obtained with three lots of test strips were compared to plasma equivalent glucose values from the YSI analyser. Lay users were also asked to rate ease of use of the FreeStyle Precision Neo system via a questionnaire.

Laboratory studies were performed at Abbott Diabetes Care to verify the performance of the FreeStyle Precision Neo system under varied test conditions.

Results: Clinical accuracy of the FreeStyle Precision Neo system was demonstrated by comparing results from 225 blood samples (from 215 subjects), tested across 3 test strip lots by trained operators, to results obtained with the YSI analyser. Results met the system accuracy requirements of ISO 15197:  

- 99.1% of results agreed within ±15 mg/dL of the reference values at glucose concentrations <75 mg/dL and within ±20% of the reference values at glucose concentrations ≥75 mg/dL

In addition, 96.4% of results agreed within ±15 mg/dL (glucose <75 mg/dL) and ±15% (glucose ≥75 mg/dL) of the reference values and 100% of results were in Zone A of the Consensus Error Grid.

Similarly, the accuracy of the FreeStyle Precision Neo system was demonstrated in the user performance (i.e. lay user) testing, with 99.4% of results within the ISO 15197 accuracy criteria. The overall mean rating for the 174 subjects completing the ease of use questionnaire was 5.5 (out of 6), demonstrating that these users found the FreeStyle Precision Neo system easy to use.

In the laboratory studies, repeatability evaluation yielded standard deviations (SD) ≤3.3 mg/dL at glucose concentrations <100 mg/dL and coefficients of variation (CV) ≤3.8% at glucose concentrations ≥100 mg/dL. Intermediate precision assessment demonstrated SDs ≤3.5 mg/dL at glucose concentrations <100 mg/dL and CV of 3.3% at glucose concentrations ≥100 mg/dL. FreeStyle Precision Neo system results were not affected by high altitude (10000 feet, 3048 meters). Additional studies demonstrated that the FreeStyle Precision Neo system provided accurate results across the claimed haematocrit range (15 to 65%) and with 28 potentially interfering substances at high concentrations.

Conclusions: The clinical studies verify accuracy of the FreeStyle Precision Neo system for fingerstick capillary testing when compared to laboratory method results – accuracy in user performance testing was demonstrated and the trained operator system accuracy evaluation met the requirements in ISO 15197:2003. The FreeStyle Precision Neo system had a high ease of use rating by first time users. Laboratory studies demonstrated that the FreeStyle Precision Neo system maintained accuracy in various challenging conditions that may be encountered in everyday home testing, including in the presence of extreme haematocrit levels and interfering substances.
Introduction

The FreeStyle Precision Neo Blood Glucose Monitoring System (here-in referred to as the FreeStyle Precision Neo system) has been designed to meet the accuracy targets expected of new blood glucose monitoring systems. The FreeStyle Precision Neo system is designed to simplify patient testing and also provides features that may ease their diabetes management – these include a large, high contrast display; a slim, lightweight design; and a 5 second test time without the need for user calibration.

The test strips, branded as FreeStyle Precision Neo Blood Glucose Test Strips, retain the TrueMeasure features of dual fill (end fill or top fill), fill trigger electrode and unique chemistry with low applied potential; the small sample volume requirement (minimum 0.6 µL); the short test time (5 seconds); the individual foil wrapping, designed to protect from exposure to moisture, chemicals or contaminants; and require no coding or calibration by the user. Use of the test strips with the FreeStyle Precision Neo system provides improved accuracy and reduced sensitivity to haematocrit compared to older Abbott Diabetes Care systems (i.e. the Precision Xtra Blood Glucose and Ketone Monitoring System).

Technology

Measurement Principle

Glucose dehydrogenase (GDH-NAD), coenzyme nicotinamide adenine dinucleotide (NAD) and an electron mediator (phenanthroline quinone, PQ) are present on the working electrodes of the test strip. Glucose in the blood sample is oxidised to gluconolactone by reaction with NAD (Figure 1). The PQ reacts with the reduced coenzyme (NADH), thus reducing the mediator and returning the coenzyme to its oxidised state (NAD). The reduced mediator is oxidised at the working electrode, this produces a small electric current which is proportional to the concentration of glucose in the sample and is measured by the meter.

Low potential measurements (Figure 2) can minimize interference by common substances & medications present in the blood sample. For an electrochemical reaction to occur, a potential (voltage) is applied between the working and reference electrodes. The larger the applied potential, the greater the number of interfering substances that can be oxidized at the working electrode and produce a false signal. The electron mediator (PQ) used in these test strips allows the electrochemical reaction to occur at low potential, so there is minimal interference with the test strip results from other substances.

Figure 2. FreeStyle Precision Neo Measurement Principle

Dual Fill

The test strip retains the dual-fill feature of previous Abbott Diabetes Care test strips that allows the user to apply blood to either the top or the end of the test strip (Figure 3). The blood is automatically drawn into the reaction area.

Summary of Features

The combination of the fill trigger electrode, the GDH-NAD chemistry with low applied electric potential and the dual fill design with visual confirmation of fill is the basis of TrueMeasure technology, designed to minimize errors from insufficient blood samples and interfering substances, allow easy sample application and thus reduce the preventable errors in glucose testing. Test strips are individually wrapped in foil packets to protect from exposure to moisture, chemicals or contamination.

In addition to the features described above, the FreeStyle Precision Neo system incorporates a number of enhancements to provide minimal sensitivity to haematocrit and high accuracy with the short (5 second) test time and no requirement for coding or calibration by the user. These features help to ensure compliance to the performance requirements for blood glucose monitoring systems and also enhance the reliability of patient testing.

Performance Evaluation

This report details a comprehensive evaluation of the FreeStyle Precision Neo system in blood glucose monitoring. A multicentre clinical study was conducted to evaluate performance with fresh capillary whole blood. Additional laboratory studies were performed to verify performance claims under various testing conditions.

Comparative Methods

The YSI 2360 Stat Plus glucose analyser served as the comparative method in the clinical and laboratory studies. The YSI whole blood glucose results were multiplied by 1.12 to obtain plasma equivalent glucose values for comparison with the test strip results. The YSI glucose analyser has metrological traceability to NIST certified reference material.

Statistical Analysis

All statistical analyses for the clinical studies were performed using SAS® version 9.2 (SAS Institute Inc., Cary, NC). Passing and Bablok regression was used to correlate meter results with comparative method values in the capillary clinical evaluation. Passing and Bablok regression analysis is recommended by the American Association of Bioanalysts2 for method comparison (accuracy) studies. Data were excluded from statistical analysis if (1) the difference between the first and second measurements of the comparative method was >4 mg/dL at glucose ≤100 mg/dL or >4% at glucose >100 mg/dL; (2) time exceeded the interval specified in the protocol (eg the BGMS and YSI tests on each sample must be completed within 20 minutes of sample collection); or (3) the data set was not complete (eg missing haematocrit level or YSI value). Laboratory study results were evaluated using JMP version 9 statistical software (SAS Institute) or higher.

Capillary (Fingerstick) Clinical Study

Materials & Method

Accuracy of the FreeStyle Precision Neo system was evaluated in two clinical studies performed at two medical centres in the United States. 174 subjects were enrolled in the first study, which included both lay user and trained operator testing. 9 subjects were excluded from the analysis due to protocol deviations, yielding 165 subjects in the first study. 50 subjects were enrolled in the second study, which included trained operator testing only, yielding 215 subjects across the studies. Samples from 10 subjects from 10 subjects were modified to provide additional samples (225 samples in total) at low (<50 mg/dL) and high (>400 mg/dL) glucose concentrations for system accuracy analysis. Blood samples collected with an appropriate anticoagulant were spiked with a 0.9% saline solution containing a high concentration of glucose to prepare high glucose samples; the spiked samples were allowed to stand for at least 15 minutes before use to allow the added glucose to equilibrate between the plasma and red blood cells. To prepare low glucose samples, blood samples collected with an appropriate anticoagulant were incubated at 27 to 37 °C to allow glycolysis to occur.

Three test strip lots were used in the studies; each sample was tested on 2 strip lots. Each strip lot tested per sample was tested by the lay user for user accuracy evaluation and ease of use survey (first study only) and in duplicate by the trained operator for system accuracy evaluation (results of the first test only are reported here, in line with guidance from the FDA). FreeStyle Precision Neo results were compared to results obtained on the YSI analyser.
Results – User Accuracy Evaluation & Ease of Use (Lay User)

The haematocrit range of the samples in this study was 25 – 51%, and the range of glucose concentrations was 43 – 358 mg/dL.

Excellent correlation was found between the FreeStyle Precision Neo system and the YSI analyser by regression analysis ($r = 0.98$, slope = 1.0, intercept = -0.4 mg/dL) – see Figure 6. Overall the mean bias from YSI reference was -0.2 mg/dL, 0.0%. Of the 165 test results (from 165 subjects), 164 (99.4%) were in Zone A (clinically accurate) and 1 (0.6%) were in Zone B (clinically acceptable) of the Consensus Error Grid – see Figure 6.

System accuracy analysis for the 3 lots combined showed: 99.1% of results agreed within ±15 mg/dL, or ±20% for glucose concentrations ≥75 mg/dL of the reference value – see Tables 5 to 7.

Results – System Accuracy (Trained Operator)

The haematocrit range of the samples in this study was 25 – 51%, and the range of glucose concentrations was 29 – 438 mg/dL.

Excellent correlation was found between the FreeStyle Precision Neo system and the YSI analyser by regression analysis ($r = 0.99$, slope = 1.01, intercept = -0.3 mg/dL). Overall the mean bias from YSI reference was 2.1 mg/dL, 1.1%. Of the 225 test results, 225 (100%) were in Zone A (clinically accurate) of the Consensus Error Grid.

System accuracy analysis for the 3 lots combined showed: 99.1% of results agreed within ±15 mg/dL, or ±20% for glucose concentrations ≥75 mg/dL of the reference value – see Tables 6 to 7.

These results illustrate that the FreeStyle Precision Neo system meets the accuracy criteria in ISO 15197.

Results

<table>
<thead>
<tr>
<th>Glucose level</th>
<th>Mean test strip response, mg/dL</th>
<th>Pooled SD, mg/dL</th>
<th>Pooled CV, %</th>
</tr>
</thead>
<tbody>
<tr>
<td>Low</td>
<td>41.0</td>
<td>3.5</td>
<td>8.6</td>
</tr>
<tr>
<td>Low-Mid</td>
<td>89.7</td>
<td>5.1</td>
<td>5.8</td>
</tr>
<tr>
<td>Mid</td>
<td>133.3</td>
<td>7.5</td>
<td>5.7</td>
</tr>
<tr>
<td>High</td>
<td>233.0</td>
<td>11.8</td>
<td>4.9</td>
</tr>
</tbody>
</table>

Haematocrit

Materials & Method

The effect of haematocrit on performance of the FreeStyle Precision Neo system was evaluated using 7 haematocrit levels, 5 glucose concentrations, 1 venous blood sample and 3 test strip lots.

The venous blood sample was adjusted to the 7 haematocrit levels (15, 20, 30, 40, 60 & 65%) by separating the plasma from the cells, then adding or removing aliquots of plasma in different proportions. The samples at each haematocrit level were divided into 5 portions and the glucose level of each sample was adjusted to the desired concentration.

30 tests (10 tests per strip lot) were performed for each of the 35 samples. Each sample was also tested on the YSI analyser and the results were used to calculate the bias of the meter results from the mean YSI reference value for each sample.

To determine haematocrit effects, the difference between the average bias (from reference value) of each test sample and the average bias (from reference value) of the control sample (42% haematocrit) was determined.

Laboratory Studies

The following studies were performed at Abbott Diabetes Care.

Precision

Materials & Method

Repeatability was evaluated using 10 meters, 3 test strip lots, and 1 venous blood sample with glucose concentrations adjusted to five concentration ranges. 10 measurements were made with each combination of meter, test strip lot and sample. Testing was completed in 1 day.

Intermediate precision was evaluated using 10 meters, 3 test strip lots and 3 levels of control solution, representing hyperglycaemic, euglycaemic and hypoglycaemic conditions. Each sample was tested in duplicate on 3 test strip lots and 10 meters on each of 20 days.

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To determine haematocrit effects, the difference between the average bias (from reference value) of each test sample and the average bias (from reference value) of the control sample (42% haematocrit) was determined.
**Results**

Results for each lot have been combined for presentation here – see Table 10. Differences in the haematocrit level of the blood sample affect results by <3.8 mg/dL at low glucose concentrations and by <7.1% at higher glucose concentrations.

**Table 10. Effect of Haematocrit**

<table>
<thead>
<tr>
<th>Glucose Level, mg/dL</th>
<th>Mean Difference in Bias from Control (42% Haematocrit)</th>
</tr>
</thead>
<tbody>
<tr>
<td>40-50</td>
<td>15  20  30  50  60  80</td>
</tr>
<tr>
<td>Haematocrit</td>
<td>mg/dL</td>
</tr>
<tr>
<td>100-120</td>
<td>%</td>
</tr>
<tr>
<td>240-230</td>
<td>%</td>
</tr>
<tr>
<td>300-350</td>
<td>%</td>
</tr>
<tr>
<td>440-460</td>
<td>%</td>
</tr>
</tbody>
</table>

The methods used in the interference studies are based on those outlined in CLSI EP-7A.

**pH**: Potential interfering effects of pH were evaluated by comparing difference in bias from reference control & test pH levels, covering the pH range 7.01 to 7.74, using venous blood in two glucose concentration ranges (50-100 mg/dL and 250-350 mg/dL) and 3 test strip lots. 10 tests were made per lot at each pH & glucose concentration.

**Results**

**Paired Difference**: The 29 potentially interfering substances undergoing paired difference testing were evaluated at concentrations above the upper limit of therapeutic or normal concentration.

For results for each test strip lot have been combined for presentation here – see Table 11. Presence of 27 substances in the blood sample affected results by <6.5 mg/dL at low glucose concentrations, therefore, at the specified test concentrations, none of these substances had an interferent effect on the FreeStyle Precision Neo system at low glucose concentrations – xylose and sodium underwent dose response testing to further evaluate potential interference from these substances at low glucose concentrations. Presence of all 29 substances in the blood sample affected results by <8% at higher glucose concentrations, therefore, at the specified test concentrations, none of these substances had an interferent effect on the FreeStyle Precision Neo system at high glucose concentrations.

**Dose Response**: The 2 potentially interfering substances undergoing dose response testing were evaluated over a range of concentrations, with the maximum test concentration being above the upper limit of therapeutic or normal concentration. The maximum concentration at which each substance did not show a clinically significant effect on performance is shown in Table 12. This maximum concentration was above the therapeutic or normal concentration for sodium, therefore this was not considered to have an effect on the FreeStyle Precision Neo system. For Xylose, the maximum concentration tested that did not show interference at low glucose concentrations was less than the therapeutic concentration (although the upper concentration calculated from the regression analysis was above the therapeutic level), therefore, a limitation is included in the test strip insert that the product should not be used during a xylose absorption test for malabsorption, where high concentrations of xylose can be present.

**pH**: Blood samples with pH across the range 7.01 to 7.74 affected results by <0.5 mg/dL at low glucose concentrations and by <1.3% at higher glucose concentrations.

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**Interference**

**Materials & Method**

29 substances have been evaluated in paired difference testing, 2 of these underwent additional dose response testing.

**Paired Difference**: 29 substances (including reducing substances, common medications, non-glucose sugars and common anticoagulants) were tested for interference using venous blood in two glucose concentration ranges (50-100 mg/dL and 250-350 mg/dL), 3 test strip lots and a paired-sample experimental design.

The glucose level of the venous blood was adjusted to the desired concentrations. Paired samples were then spiked with a concentrated solution of the substance (test sample) and an equal volume of the solvent used to dissolve the substance (control sample). This was repeated for each potentially interfering substance. 30 tests (10 per test strip lot) were made per sample. The YSI analyser was used to assign glucose reference values to the samples.

For each sample, the bias of the average measured values (test strip results) from the mean YSI reference value was determined. The difference in bias between test and control samples was then calculated for each substance.

**Dose Response**: 2 substances were tested for interference using venous blood at the low glucose concentration range (50-100 mg/dL), 3 test strip lots and a dose response experimental design.

The glucose level of the venous blood was adjusted to the desired concentration. The sample was then divided into aliquots which were spiked with different concentrations of the substance or an equal volume of the solvent used to dissolve the substance (control sample). This was repeated for the 2 potentially interfering substances. 30 tests were made per sample. The YSI analyser was used to assign glucose reference values to the samples.

A regression model was fit between the mean bias (across lots) to control and the interferent concentration. The regression model was used to calculate the upper concentration limit for no interference from the substance (bias from control within 10%).

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**Table 11. Paired Difference Interference Testing**

<table>
<thead>
<tr>
<th>Substance</th>
<th>Upper Limit of Therapeutic or Physiological Concentration, mg/dL</th>
<th>Test Concentration, mg/dL</th>
<th>Mean Difference in Bias from Control</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acetamiprid</td>
<td>3</td>
<td>20</td>
<td>0.3</td>
</tr>
<tr>
<td>Amoxicillin</td>
<td>2.5</td>
<td>7.5</td>
<td>-2.0</td>
</tr>
<tr>
<td>Ascorbic acid</td>
<td>1.5</td>
<td>2.5</td>
<td>2.8</td>
</tr>
<tr>
<td>β-hydroxybutyrate</td>
<td>&lt;7.6</td>
<td>265</td>
<td>-1.3</td>
</tr>
<tr>
<td>Bilirubin (unconjugated)</td>
<td>1.2</td>
<td>20</td>
<td>0.9</td>
</tr>
<tr>
<td>Captopril</td>
<td>0.1</td>
<td>0.5</td>
<td>-0.3</td>
</tr>
<tr>
<td>Cholesterol</td>
<td>&lt;200</td>
<td>500</td>
<td>6.5</td>
</tr>
<tr>
<td>Creatinine</td>
<td>1.3</td>
<td>5</td>
<td>5.3</td>
</tr>
<tr>
<td>Dopamine</td>
<td>0.03</td>
<td>0.1</td>
<td>1.2</td>
</tr>
<tr>
<td>EDTA</td>
<td>180</td>
<td>720</td>
<td>0.3</td>
</tr>
<tr>
<td>Erythritol</td>
<td>0.01</td>
<td>10</td>
<td>2.2</td>
</tr>
<tr>
<td>Glucose</td>
<td>20</td>
<td>15</td>
<td>0.7</td>
</tr>
<tr>
<td>Gentisic acid</td>
<td>0.6</td>
<td>1.8</td>
<td>0.7</td>
</tr>
<tr>
<td>Heparin</td>
<td>1500</td>
<td>5600*</td>
<td>-0.1</td>
</tr>
<tr>
<td>Ibuprofen</td>
<td>0.7</td>
<td>50</td>
<td>6.0</td>
</tr>
<tr>
<td>Lactate</td>
<td>20</td>
<td>59</td>
<td>3.9</td>
</tr>
<tr>
<td>Lactose</td>
<td>-</td>
<td>100</td>
<td>1.3</td>
</tr>
<tr>
<td>L-dopa</td>
<td>0.2</td>
<td>5.0</td>
<td>4.9</td>
</tr>
<tr>
<td>Maltose</td>
<td>100-120</td>
<td>110</td>
<td>1.5</td>
</tr>
<tr>
<td>Methyldopa</td>
<td>0.75</td>
<td>1.5</td>
<td>1.0</td>
</tr>
<tr>
<td>Niacin</td>
<td>0.9</td>
<td>10</td>
<td>-1.8</td>
</tr>
<tr>
<td>Salicylic acid</td>
<td>30</td>
<td>60</td>
<td>3.0</td>
</tr>
<tr>
<td>Sodium</td>
<td>414</td>
<td>500</td>
<td>-8.4</td>
</tr>
<tr>
<td>Tetracycline</td>
<td>0.5</td>
<td>1.5</td>
<td>-1.7</td>
</tr>
<tr>
<td>Tolazamide</td>
<td>2.8</td>
<td>15</td>
<td>1.6</td>
</tr>
<tr>
<td>Trubutamide</td>
<td>10</td>
<td>64</td>
<td>4.1</td>
</tr>
<tr>
<td>Triglyceride</td>
<td>&lt;150</td>
<td>1500</td>
<td>0.5</td>
</tr>
<tr>
<td>Uric acid</td>
<td>7.2</td>
<td>24</td>
<td>1.9</td>
</tr>
<tr>
<td>Xylose</td>
<td>58</td>
<td>100</td>
<td>15.6</td>
</tr>
</tbody>
</table>

**Table 12. Dose Response Interference Testing**

<table>
<thead>
<tr>
<th>Substance</th>
<th>Upper Limit of Therapeutic or Normal Concentration, mg/dL</th>
<th>Maximum Test Concentration, mg/dL</th>
<th>Upper Concentration at Which There is No Interference, mg/dL</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sodium</td>
<td>414</td>
<td>500</td>
<td>478</td>
</tr>
<tr>
<td>Xylose</td>
<td>58</td>
<td>100</td>
<td>57</td>
</tr>
</tbody>
</table>

Based on maximum concentration tested that showed bias ≤0.10 mg/dL.
Altitude

Materials & Method

The effect of altitude on the performance of the FreeStyle Precision Neo system was evaluated at 2 altitudes (sea level and 10000 feet; 3048 meters), using 3 venous blood samples (from different subjects), 3 glucose concentrations and 3 test strip lots. 30 tests (10 tests per strip lot) were performed for each of the 18 samples. Each sample was also tested on the YSI analyser and the results were used to calculate the bias of the meter results from the mean YSI value for each sample. To determine altitude effects, the difference between the average bias (from reference) of the testing performed at high altitude and the average bias of the control samples (sea level) was determined.

Results

High altitudes of up to 10000 feet (3048 meters) affect results by ≤2.3 mg/dL at low glucose concentrations and by ≤3.5% at higher glucose concentrations.

The FreeStyle Precision Neo system minimizes the potential for interference. Use of GDH-NAD ensures high specificity of the test to glucose. Consequently, there is no interference from other sugars such as galactose and maltose in dialysis patients that use icodextrin-containing solution for dialysis. The FreeStyle Precision Neo system should not be used during xylose ingestion testing due to the xylose interference also minimising interference from reducing substances commonly found in the blood, such as acetaminophen (paracetamol) and uric acid. Each of the substances tested had no clinically significant effect on FreeStyle Precision Neo results (with the exception of xylose as noted above).

Convenience and Ease of Use

The FreeStyle Precision Neo system is designed to be easy and convenient to use for frequent monitoring of blood glucose:
- Rated easy to use by first time users. The overall mean rating by 174 lay users was 5.5 (on a scale of 1 to 6).
- Requires no calibration or coding by the user.
- Has a fast test time & requires a small blood sample. The FreeStyle Precision Neo system takes only 5 seconds per test and requires a small sample (0.6 µL minimum).
- Allows easy application of blood. The user can apply blood to the top or the end of the test strip and the blood is automatically drawn into the reaction site. The design provides equal convenience to left-handed and right-handed users and the features make testing easier for caregivers or users with limited dexterity.
- Autostarts when the sample is detected.
- Allows re-application of sample. If the test does not start after the first application of blood, a second sample of blood can be applied to the same test strip within 5 seconds.

Reduced Use Error

Use error is a major concern in home glucose monitoring. The FreeStyle Precision Neo system is designed to reduce use error in everyday testing conditions:
- Reduce risk associated with underfilling test strips. Error results ranging from 85% lower to 39% higher have been reported when a small drop of blood is used with some blood glucose monitoring systems.\(^9,10,11\)
- The sample detection (fill trigger) electrode in test strips used with the FreeStyle Precision Neo system ensures that the test only starts when sufficient sample is applied, minimising the potential for error from ‘short’ sampling. Furthermore, the fill confirmation window (via the semi-opaque tape layer) allows the user to confirm sufficient sample is applied before they withdraw their finger from the test strip.
- Individually foil wrapped. Exposure of test strips in a vial to air and moisture is common, for example if vials are not capped promptly and tightly after each opening. Test strips exposed to air for as little as 2 hours have been shown to cause a -26% bias.\(^12\)
Each FreeStyle Precision Neo test strip is individually wrapped in easy to open foil, to protect it against air, moisture and other contaminants.

Conclusions

In conclusion, the studies described in this paper show that the FreeStyle Precision Neo system delivers accurate, reliable glucose results whilst providing safeguards to ensure the integrity of the testing process. Specifically, the clinical studies demonstrated the accuracy of the FreeStyle Precision Neo system for capillary self-testing – accuracy of the system in the hands of the lay user and trained operators meets the accuracy criteria in ISO 15197. In user performance testing, the FreeStyle Precision Neo system had a high acceptance and ease of use rating among first-time users. Laboratory studies showed that the test strip performs well in the presence of interfering substances and across the wide claimed haematocrit range (15 to 65%). Combined with features that can minimise short sampling and test strip contamination, the short test time and no requirement for coding or calibration by the user, these results show that the FreeStyle Precision Neo system is uniquely designed to provide accurate and reliable results in self-testing by people with diabetes.

Discussion

The FreeStyle Precision Neo system has demonstrated excellent performance throughout the evaluations reported here. The clinical, user and laboratory studies illustrate that the FreeStyle Precision Neo system has excellent accuracy and ease of use.

Reliable and Accurate Results for Home Monitoring

Accuracy was verified with capillary blood samples across the measurement range of the FreeStyle Precision Neo system, the haematocrit range of 15 to 65%, at high altitude (10000 feet; 3048 meters), and in the presence of 28 potentially interfering substances.

The FreeStyle Precision Neo system delivers accurate results from fingertip capillary samples in testing by trained operators and lay users; >99% of results were in the “clinically accurate” Zone A of the Consensus Error Grid and >99% were within the ISO 15197 accuracy criteria for both user groups.

References

11. Lawandowski KB, Dan L. Effects of small sample volumes and interfering substances on two glucose meters. Diabetes 1999;48:A102