

# **Quality Evaluation of the New PTS Diagnostics™ Capillary Tubes (glass/plastic) Compared to the Current PTS Diagnostics Portfolio: CardioChek Capillary Tubes (heparinized glass/plunger) and Capillary Blood Collectors (plastic)**

## **Medical Division, PTS Diagnostics**

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### **Purpose**

Three studies were conducted to compare the new PTS Diagnostics™ capillary tubes to the CardioChek capillary tubes (heparinized glass/plunger) and the plastic capillary blood collectors to determine if the three different styles are overall statistically equivalent in precision and accuracy using multiple types of PTS Diagnostics test strips. The potential to over-fill or under-fill the capillary tubes was evaluated. Timed blood collection testing was performed on both the new PTS Diagnostics capillary tubes and the heparinized glass/plunger tubes to determine the effect of time of retention of sample on both the potential for clotting, and any effect on accuracy and precision.

### **History**

The new PTS Diagnostics capillary tubes are non-coated glass tubes externally covered in plastic with a vented plastic bulb. Initially, an internal study was conducted to determine if the PTS Diagnostics capillary tubes would pass the PTS Diagnostics incoming inspection criteria. The 15µL, 30µL and 40µL PTS Diagnostics capillary tubes passed the incoming inspection of micropipettes, glass heparin tubes and plungers guidelines. All of the tube volumes were within the ±10% guidelines of the stated volume.

A PTS Diagnostics research study was conducted to test the new PTS Diagnostics capillary tubes to determine if the tubes were overall statistically equivalent in precision and accuracy to the plastic capillary blood collectors when testing with PTS Panels® CHOL+HDL+GLU test strips and glucose test strips on a CardioChek® PA analyzer. The results demonstrated overall statistical equivalency between the PTS Diagnostics capillary tubes and the plastic capillary blood collectors. The comparison demonstrated equivalence in accuracy and precision for both the 40 µL and the 15 µL PTS Diagnostics capillary tubes versus the 40 µL and the 15 µL plastic capillary blood collectors.

A PTS Diagnostics research study showed the precision and accuracy results between the PTS Diagnostics capillary tubes and the glass capillary tubes with plungers were overall statistically equivalent when testing PTS Panels® CHOL+HDL+GLU test strips. For the timed blood collection study, these two versions of capillary tubes performed with statistical equivalence as well. Micro clotting was observed by the technician at one minute and at three minutes of testing, but not at <30 seconds, in the samples of two subjects (out of 30 samples) in the

PTS Diagnostics capillary tubes. Micro clotting was not observed in the <30-second samples. It is important to note that there was no indication of an effect on analyte measurements in the timed study, nor was there any indication of effect of potential clotting in the precision and accuracy studies each involving 20 replicate samples.

A research study was completed to further investigate testing times and the possibility of over-fill or under-fill with the PTS Diagnostics capillary tubes compared to the heparinized glass/plunger capillary tubes. Additionally, testing on PTS Panels lipid panel test strips was conducted to include triglycerides, which had not yet been tested using the PTS Diagnostics capillary tubes.

The precision data (with 20 repetitions) for both types of capillary tubes was statistically equivalent for cholesterol, HDL and triglycerides. While the cholesterol, HDL cholesterol and triglyceride accuracy results (with 20 repetitions) for both types of capillary tubes were clinically equivalent, for one sample (the low HDL of 27 mg/dL), the PTS Diagnostics capillary tubes demonstrated an average percent recovery of 115.55%, which is not within the  $\pm 12\%$  expectation for HDL cholesterol. The heparinized glass/plunger capillary tubes recovery for the same sample was 108.52%.

The timed study, comparing <30 seconds to 10 minutes, demonstrated that testing can be performed when the sample is retained in the PTS Diagnostics capillary tube/CardioChek capillary tubes (heparinized glass/plunger) for ten minutes after the blood collection with little to no effect on the cholesterol and HDL cholesterol. The triglycerides were the chemistry which were most influenced when the blood stayed in the capillary for ten minutes after collection. The

heparinized glass/plunger capillary tubes at 10 minutes demonstrated blood clots for 5 (of 40) of the samples. The PTS Diagnostics capillary tubes demonstrated blood clots for 7 (of 40) of the samples, and the backs of the test strips appeared spotty for 3 of the samples. The PTS Diagnostics capillary tubes produced 3 (out of 40 samples, including the 7 with clots) test errors with no results given on the analyzer.

The over-fill testing proved difficult to perform. The technician attempted 10 times to over-fill the PTS Diagnostics capillary tubes but stated that she was not able to over-fill them. The technician over-filled the heparinized glass/plunger capillary tubes by moving the white stopper in the tube, which takes effort. The results for the testing were statistically equivalent.

The under-fill testing was subjective. The technician under-filled the PTS Diagnostics capillary tubes and the heparinized glass/plunger capillary tubes by filling 50 to 75% instead of 100% as recommended. The triglycerides were the chemistry affected the most by the lower volume of sample with the PTS Diagnostics capillary tubes demonstrating 80% recovery compared to 83% recovery with the heparinized glass/plunger capillary tubes.

The overall conclusions for the study were that the results were statistically equivalent for both types of capillary tubes when the sample was dispersed onto the test strips in <30 seconds. There was not a statistical difference in the number of tubes demonstrating blood clotting at 10 minutes of retention when comparing PTS Diagnostics capillary tubes to heparinized glass/plunger capillary tubes. Tests could be performed when samples were held for 10 minutes in either tube with the heparinized glass/plunger capillary tubes being only slightly (but not statistically) better than the PTS Diagnostics

capillary tubes. Ideal testing occurs when samples are retained within the capillary tubes for less than 30 seconds.

### **Conclusions**

The use of the new PTS Diagnostics capillary tubes provides statistically and clinically equivalent precision and accuracy test results when compared to both the heparinized glass/plunger capillary tubes and plastic capillary blood collectors. Although there is minimal impact on test results with 1, 3 and 10-minute sample retention times in the tubes, best results are obtained when the sample is dispensed within 30 seconds. There was no statistical difference in the number of tubes with blood clotting between the PTS Diagnostics capillary tubes and the CardioChek capillary tubes (heparinized glass/plunger). Potential micro clotting did not significantly affect test procedures. Best practice recommendations for the PTS Diagnostics capillary tubes, as well as any other capillary tube, is to collect and dispense the blood sample within 30 seconds.



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