**Professional Procedure Guide**

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**Introduction**
- If the temperature label, placed on the outside of every kit, is removed or a new temperature in excess of 30°C (86°F) is noted on the label, this kit should not be used.
- Run the test with all parts of test kit at the same temperature within the specified range.
- If the kit has recently been at high temperatures (above 45°C / 113°F), the reagent bottle should be at room temperature for at least one hour before use.
- Avoid running the test in direct sunlight, on hot or cold surfaces, or near sources of heat or cold.

**Note:**
- All instances of the box or pouches in this kit must match. The product should not be used.

**Match Lot Numbers**
- The analyser only works with the materials included in the original lot. The analyser will display a “00 TL.”

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**Open Plastic Shaker Pouch**
1. Tear plastic pouch open at the perforation line.

**Note:**
- This pouch may be used if the kit has been at high temperatures (above 45°C / 113°F). Run the test with all parts of the test kit at the same temperature within the specified range.

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**Open Foil Cartridge Pouch**
2. Tear foil pouch open at the perforation line.

**Note:**
- This pouch may be used if the kit has been at high temperatures (above 45°C / 113°F). Roll the test with all parts of the test kit at the same temperature within the specified range.

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**Insert Cartridge**
3. Insert Cartridge into Cartridge
- Push down completely to dispense diluted sample.

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**Dispense Sample into Cartridge**
4. Dispense Sample into Cartridge
- Push down completely to dispense diluted sample.

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**Prepare Shaker**
5. Prepare Shaker
- Tear off top of pouch and hi-lo-

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**Insert Blood Collector**
6. Insert Blood Collector
- Fully insert blood collector into shaker body.

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**Dispose of Cartridge / Save Analyzer**
7. Dispose of Cartridge / Save Analyzer
- Dispose of in accordance with your local regulations.

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**Match Lot Numbers**
8. Match Lot Numbers
- Analyzer and test cartridge codes must match.

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**Collect Blood**
9. Collect Blood
- Use your own lancet device to draw blood.
- Gently touch blood drop to fill both channels of the blood collector.

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**Verify Blood Amount**
10. Verify Blood Amount
- Carry both channels are completely filled.

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**Dispose Cartridges / Save Analyzer**
11. Dispose Cartridges / Save Analyzer
- Dispose of in accordance with your local regulations.

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**Temperature Guidelines**
- Use at room temperature 18-28°C (64-82°F)
- Use within 2 minutes of opening.
- Do not use if foil pouch is damaged.

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**Follow these instructions carefully.**
Each test cartridge houses 2 dry-reagent strips containing measured and reported in ng/mL.

The amount of cotinine present in the collected sample is determined by the PTS Detect cotinine system using competitive immunometric assay containing a specific anti-cotinine antibody conjugated to blue particles which are captured on the detection zone in the presence of the diluted blood sample and the specific anti-cotinine antibody. The amount of blue particles captured on the detection zone is directly proportional to the amount of cotinine in the diluted blood sample. The PTS Detect cotinine system quickly quantifies cotinine at concentrations ranging from 25 – 200 ng/mL.

The PTS Detect cotinine system uses a competitive immunoassay and is well suited to environments such as healthcare providers’ offices and clinics, schools, and other public environments where time is a critical factor.

Cotinine can be measured by a variety of techniques on many sample types including blood, urine, saliva, and breath. The PTS Detect cotinine system is available for urine and saliva tests. Laboratory methods exist for the determination of cotinine in whole blood, serum, plasma, and urine. Point-of-care devices exist for the determination of cotinine in whole blood, serum, plasma, and urine. Cotinine is used to assess nicotine exposure in humans due to its stability in most sample types, availability of appropriate sterile and disposable lancet or venipuncture/sampling supplies, and high specificity for nicotine exposure. The PTS Detect cotinine system provides accurate and rapid cotinine quantification on whole blood, serum, or plasma samples.

Cotinine has a half-life of 4 – 6 days, which is longer compared to nicotine, and therefore, can provide a more accurate determination of recent nicotine exposure.

The PTS Detect cotinine system provides rapid turn-around-time from sampling to result. Cotinine has a longer half-life (4 – 6 days) than nicotine, which allows for more accurate assessment of recent smoking and better monitoring of programs to reduce smoking.

Cotinine by competitive immunoassay (immunoassay test) is well suited to determine recent or ongoing nicotine exposure.

Storage and shipping of PTS Detect cotinine system

The PTS Detect cotinine system is available as PTS Detect cotinine system analyzer (1), PTS Detect cotinine system test cartridges and shaker kits (10), operating and error codes (OR = Out of Range; QC = Quality Control; E1 to E99 = all other error codes), and user operation manual (1). All components of the PTS Detect cotinine system may be exposed to biohazardous material. Use universal precautions and dispose of all components after the foil pouch is opened.

Operating conditions

The PTS Detect cotinine system is designed for use at room temperature (18°C – 28°C / 64°F – 82°F). Store in refrigerator (2 – 8°C / 36 – 46°F). Analyzers, test cartridges, and shaker kits must be at room temperature before using. Do not mix pouches and analyzers from different lots. Refrigerated (2 – 8°C / 36 – 46°F). Analyzers, test cartridges, and shaker kits must be at room temperature before using. Do not mix pouches and analyzers from different lots.

Accuracy

The accuracy of the PTS Detect cotinine system was examined by immunoassay analysis performed using 41 – 199 ng/mL cotinine concentrations. The accuracy was evaluated by first, second, and third order polynomial fits to determine the linearity of response over the range of concentrations. Observed results were evaluated by first, second, and third order polynomial fits.

The mean serum cotinine concentration in non-smokers was 0.08 ng/mL, with a 95% confidence interval of 0.07 ng/mL, and 0.16 ng/mL, respectively.

Average cotinine values vary slightly based on ethnicity, with non-smokers exhibiting mean values of 0.08 ng/mL, 0.16 ng/mL, and 0.30 ng/mL for non-Hispanic white, black, and other ethnicities, respectively.

The PTS Detect cotinine system was evaluated by performing 44 analyses on 12 different lots of cotinine. The overall accuracy of the PTS Detect cotinine system in 12 different lots was evaluated by performing 44 analyses on each of these lots. The overall accuracy of the PTS Detect cotinine system across lots was 3.47% at the low level and 2.53% at the high level.

Preanalytic interfering substances

The studies showed no effect from any of these potential interferents on test performance.

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Detection and identification

The PTS Detect cotinine system and its components are biohazardous materials and must be disposed of properly. Follow your local regulations for biohazardous materials.

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