State of North Dakota)
)ss
County of Burleigh)

I, Janelle Portscheller, do hereby certify that I am a duly-appointed State Toxicologist for the State of North Dakota and an official custodian of the records and files of the office thereof, and designee of the Director of the North Dakota Office of the Attorney General, Crime Laboratory Division, and authorized for biological alcohol, carboxyhemoglobin, and drug analysis, to approve chemical analysis methods, devices, instruments and certify individuals to conduct chemical analysis; determine the qualifications or credentials for being medically qualified to draw blood; issue lists of approved designations and devices; and sign and certify records of the North Dakota Office of Attorney General, Crime Laboratory Division, and that I have carefully compared the

APPROVED METHOD FOR OPERATING THE ABBOTT SOTOXA ORAL FLUID MOBILE ANALYZER (Document ID: 9325 Revision 4)

hereto attached with the respective original as the same appears of record on file in the Office of Attorney General, Crime Laboratory Division, in the County of Burleigh, North Dakota, and find the same to be a true and correct copy thereof and of the whole thereof, which approved method has remained continually in effect without interruption since its beginning September 16, 2024, and will continue to be approved and in effect unless and until a revised approved method has been approved. In witness whereof I have set my hand at the city of Bismarck, in said county this:

16th day of September, 2024

Janelle Portscheller
Janelle Portscheller, State Toxicologist

State of North Dakota)
)ss
County of Burleigh)

On this 16th day of September, 2024, before me personally appeared Janelle Portscheller, known to me to be the State Toxicologist for the North Dakota Office of Attorney General, Crime Laboratory Division, and acknowledged to me that she has executed the same.

Subscribed to and sworn before me this:

16th day of September, 2024

Deanna Dailey
Deanna Dailey, Notary Public, State of North Dakota
My Commission Expires March 23, 2027

DEANNA DAILEY
Notary Public
State of North Dakota
My Commission Expires Mar 23, 2027

Notary seal/stamp

NORTH DAKOTA OFFICE OF ATTORNEY GENERAL
CRIME LABORATORY DIVISION

APPROVED METHOD FOR OPERATING THE ABBOTT SOTOXA ORAL FLUID MOBILE ANALYZER

SCOPE:

Operation of the Abbott SoToxa Oral Fluid Mobile Analyzer. The Abbott SoToxa Oral Fluid Mobile Analyzer is a roadside oral fluid drug screening device.

SAFETY:

The Abbott SoToxa Oral Fluid Mobile Analyzer and SoToxa Test Cartridges generate a weak magnetic field. The magnetic field may interfere with the operation of cardiac implant devices such as pacemakers. Maintain a safe distance between the SoToxa Mobile Analyzer and the SoToxa Test Cartridges and implanted devices. Note: The test operator and not the subject will be in contact with the SoToxa Mobile Analyzer and the SoToxa Test Cartridges. The subject will be in contact with the SoToxa Oral Fluid Collection device which does not generate a magnetic field.

PROCEDURE:

A. Ascertain the subject has nothing to eat, drink or smoke 10 minutes prior to providing an oral fluid sample.

B. Turn on the SoToxa Mobile Analyzer by pressing the power button on the right-hand side of the unit. Note: The operational temperature of the unit is 41 to 91 ^{o}F. If the unit is outside this temperature range a message will appear on the display screen indicating the temperature is outside of the acceptable range. If this message appears allow for at least 30 minutes for the analyzer to reach ambient temperature before use.

C. Quality Control Tests
   1. The quality control tests shall be run prior to each subject test.
   2. Insert the Positive Quality Control (PQC) test cartridge into the analyzer. The cartridge will automatically be analyzed.

a. If the Positive Quality Control (PQC) quality control test passes, the analyzer will display a message for the Positive Quality Control (PQC) test cartridge to be removed and the Negative Quality Control (NQC) test cartridge to be inserted into the analyzer.
b. If the Positive Quality Control (PQC) quality control test fails a message of "QC Results: Fail" will be displayed. Do not proceed with testing and contact Abbott SoToxa Customer Service.
c. Remove the Positive Quality Control (PQC) test cartridge from the analyzer.

3. Insert the Negative Quality Control (NQC) test cartridge into the analyzer. The cartridge will automatically be analyzed.
   a. If the Negative Quality Control (NQC) quality control test passes, a message of "QC Results: Pass" will be displayed.
   b. If the Negative Quality Control (NQC) quality control test fails a message of "QC Results: Fail" will be displayed. Do not proceed with testing and contact Abbott SoToxa Customer Service.
   c. Remove the Negative Quality Control (NQC) test cartridge from the analyzer.

D. Oral Fluid Sample Analysis
1. When the analyzer is ready to start a test, a message of "Waiting for Cartridge Insertion" will appear on the display screen.
2. Remove the SoToxa Test Cartridge from the foil wrapper. Check the color of the silica gel packet within the foil wrapper.
   a. If the silica gel packet is amber in color proceed with the test.
   b. If the silica gel packet is green in color discard the test cartridge and open a new SoToxa Test Cartridge.
3. Insert the test cartridge into the analyzer unit. The analyzer will automatically read the barcode on the test cartridge and verify the test cartridge expiration date.
   a. If the test cartridge is not expired a message of "Cartridge Valid" will appear.
   b. If the test cartridge is expired a message of "This Cartridge has Expired" will appear. Remove and discard the test cartridge. Find and insert a non-expired test cartridge.
4. Instruct the subject to remove the SoToxa Oral Fluid Collection device from the foil wrapper.
5. While only holding the plastic stem of the collection device, have the subject insert the collection device into their mouth. Have the subject actively swab the collection device around their gums, tongue, and cheeks until the sample presence indicator starts to turn blue.
6. Insert the collection device into the test cartridge. Push the collection device all the way into the test cartridge.

7. The analyzer screen will display a message “Test in progress” and a countdown timer will appear.
    a. The analyzer unit must remain level and still during the testing.
    b. If the analyzer unit is not level the Tilt sensor will display a warning on the screen when the analyzer is tilted beyond the acceptable range.
    c. If the tilting is not immediately corrected a test error message will occur and no results will be given. Repeat the Quality Control Tests (see part C) and the above Oral Fluid Sample Analysis steps.
8. Once the test has been processed by the analyzer, the results screen will be displayed for each drug category tested.
    a. Results
        1. Negative – The drug concentration in the oral fluid sample is below the cutoff concentration for the drug category.
        2. Positive – The drug concentration in the oral fluid sample exceeds the cutoff concentration for the drug category.
        3. Invalid – Results could not be provided for the drug category. If Invalid appears for all the drug categories, the officer may wait an additional 10 minutes before collecting another oral fluid sample as an interferent may have caused an invalid test. Remove the test cartridge from the analyzer and repeat the Quality Control Tests (see part C) and the above Oral Fluid Sample Analysis steps.
    b. Click “OK.”

E. Printing the results
1. Connect the printer to the analyzer if it is not already connected.
2. Power on the printer.
3. A message of “Do you wish to print the results” will be displayed on the screen. Select “Yes” to print the results.
4. If a message “Print Failure” appears check if the printer is powered on and the printer is connected to the analyzer.
    a. Select “Retry” to return to the previous screen.
    b. If printing is not required select “No.”
5. Results are also stored in the device and can be printed at a later time. If the results are printed at a later time.
    a. Click Menu.
    b. Select View Results then OK.
    c. Find and select the stored result.
    d. Click Options.
    e. Select Print then OK.

f. If results are printed at a later time a message of "Stored Test Results" will appear on the printed test results.

6. The test operator will fill in their name and the subject's name on the printed results. No signatures are required on the printed results.

F. A message of "Waiting for Cartridge Removal" will appear on the screen. Remove the test cartridge from the analyzer. Do not remove the collection device from the test cartridge. Dispose the test cartridge with the collection device.

G. Printing Quality Control Tests.

1. Click Menu.
2. Select View Results then OK.
3. Find and select the stored Positive Quality Control (PQC) result.
4. Click Options
5. Select Print then OK.
6. Repeat the above steps for the stored Negative Quality Control (NQC) result. Note: The Negative Quality Control (NQC) may be printed before the (PQC).

H. Analyzer servicing

1. The analyzers will be serviced by Abbott SoToxa or authorized representative with the frequency of servicing determined by Abbott.
2. The test results and quality control results printout will indicate the Analyzer's status as "OK" or "Service Required."
3. A test will still be considered valid if the Analyzer's status is "Service Required" but both the Positive Quality Control (PQC) and Negative Quality Control (NQC) have results of "Pass."

FURTHER INFORMATION:

A test administered according to the above procedure, and/or the Abbott SoToxa Oral Fluid Mobile Analyzer – User Guide, shall be deemed to be in accordance with the Approved Method.

REFERENCES:

Abbott SoToxa Oral Fluid Mobile Analyzer – User Guide. Alere Toxicology Plc, 21 Backlands Way, Abingdon, Oxfordshire OX14 1 DY, UK (T): +44 (0)1235 861 291.