

MECTEST

The Simplest Way to Meconium Drug Testing

Question: Is meconium drug testing more sensitive than urine testing?

Answer: Yes. The evidence is overwhelming that meconium drug testing has a higher sensitivity for drug detection than urine testing.

Question: What do you think about hair analysis for drug testing in the newborn infant?

Answer: Mectest is not used for hair analysis. As for hair analysis, there are some disadvantages to the procedure, due to passive contamination of hair and that hair collection is an invasive procedure. Also, not all babies are born with ample hair for analysis.

Question: Can Mectest be used for enzyme immunoassay such as Enzyme Multiplied Immunoassay Technique (EMIT) and Fluorescence Polarization Immunoassay (FPIA)?

Answer: Yes. The Mectest Processor can be used to prepare the meconium analyte for analysis by EMIT, FPIA or RIA. The paper of Dr. Ostrea on mass screening, published in the Journal of Pediatrics, 1994, used the Mectest Processor to prepare the meconium samples for analysis by EMIT or FPIA. The Mectest Processor is the only medical device cleared by the food and Drug Administration for clinical applications in meconium drug testing in conjunction with Radioimmunoassay (RIA), Enzyme Multiplied Immunoassay Technique (EMIT) or Fluorescence Polarization Immunoassay (FPIA).

Question: How should meconium samples be collected and handled for analysis by Mectest?

Answer: The meconium can be collected directly from the infant's diaper. Mix the meconium in the diaper well and get an aliquot using the built-in spoon (cap with scoop of feces container) from the Mectest processor. Cap the processor, label and send the sample to the laboratory where it should be vortexed to achieve an even dispersion of the meconium in the solvent. Once meconium is dispersed in the solvent, there is no need to refrigerate the sample, if analysis is to be done within 72 hours.

Question: What may contribute to a false negative result (e.g., mother admits to drug use, yet meconium drug test is negative)?

Answer: A false negative reading is often due to a problem from meconium sampling. There should always be enough meconium to fill a heaping of the collecting spoon. If there is not enough meconium scooped out, the results may be negative due to insufficient material analyzed. Similarly, a higher positive yield can be achieved by collecting meconium from two diapers. The samples can be mixed into one, and then test samples obtained from this mixture.

Question: If meconium cannot be immediately processed and analyzed, how should the sample be stored?

Answer: Meconium should be collected in a plastic container and kept in a freezer until the time of analysis. Meconium analysis can be done on batched samples.

- Question: How does meconium testing by radioimmunoassay (Mectest) compare with EMIT or FPA?
- Answer: Testing by radioimmunoassay is the most sensitive method of analyzing meconium for drugs. However, for practical purposes, the cut off sensitivity level used by EMIT or FPA will suffice for clinical purposes.
- Question: Can confirmation of Mectest positive results be done by EMIT or FPA?
- Answer: Strictly speaking, confirmation of positive results must be done using other diagnostic methods. Since radioimmunoassay, EMIT or FPA are immunoassays, the suggested confirmation method is either thin layer chromatography or GC/MS.
- Question: How long does analysis by Mectest take before results are known?
- Answer: Once meconium is analyzed using Mectest, the results can be obtained within 4-5 hours. The most common cause of delay in meconium analysis is the batch testing of multiple samples. If this occurs, the hospital need not delay the discharge of infants who are awaiting the results of the meconium drug test. Once the results of the test are obtained, a CD 3200 is filed with the Child Protective Services, on those who had a positive drug test, so that the home situation of the infant can be investigated appropriately.
- Question: Is meconium testing accepted in Court?
- Answer: Yes, More and more, the public and physicians are aware that the meconium drug test is a far more sensitive and specific test, than urine testing, to detect illicit intrauterine drug exposure of newborn infants.
- Question: Can Mectest be used for other illicit drugs, such as valium?
- Answer: The Mectest has been cleared by the FDA only for the detection of cocaine, opiate and cannabinoid. Future developments of Mectest will include the other drugs of abuse.
- Question: How sensitive is Mectest?
- Answer: Mectest is 85% sensitive. (Note: Sensitivity applies to the positive reading. Hence, if the analytical result using Mectest is positive, there is an 85% chance that the result is positive.)
- Question: What is the specificity of Mectest?
- Answer: The specificity of Mectest is 99 to 100%. (Note: Specificity of Mectest applies to a negative reading. Hence if the analytical result using Mectest is negative, 99 to 100% of the time, the reading is in fact negative.)
- Question: What advantages does meconium drug analysis using Mectest offer over urine analysis?
- Answer: Urine analysis is not a practical method to use to determine the exposure of newborn infants to drugs in utero. Considering the very low specificity of urine analysis the test is no more than 50% accurate. A negative reading does not necessarily mean the infant was not exposed to drugs in utero. Additionally, timing in urine collection is critical. Urine analysis may not detect the presence of drugs if the mother stopped taking the drug weeks before the urine collection. Drug metabolite in meconium, on the other hand, may be detected from the 12th week of gestation. The risk of contamination during and following the collection of urine is greater than with meconium. The stability of meconium once collected is ideal for serial or batch testing. Meconium if left in

the feces container with the Mectest solvent can be analyzed within 72 hours without refrigeration. Meconium, as is, can be frozen indefinitely.

Question: What is the cost of meconium drug testing using Mectest?

Answer: Meconium drug testing using the Mectest Processor translates to about \$4.30 - \$6.45 per test, per drug plus the cost of the EMIT, FPIA or the RIA kits, depending on what method is employed. Needless to say, there is the added benefit of enabling hospitals to run the test within the confines of their laboratories. More than just the convenience of doing meconium drug testing in hospital laboratories, the Mectest kit allows hospital facilities to establish adequate control procedures and therefore, minimize the risk of contamination, loss or mixing of samples.

Question: What are the cut-off concentrations of Mectest? (Lower limit, i.e., the least amount of drug that can be detected from meconium using Mectest.)

Answer: The cut-off concentrations of Mectest for the following drugs are as follows:

1. Cocaine 7.62 ng/ml
2. Opiate 27.82 ng/ml
3. Cannabinoid 6.54 ng/ml

Question: Can Mectest be used to detect Methamphetamines?

Answer: Mectest has been cleared by the US FDA for the analysis of cocaine, opiate and cannabinoid only. However, Dr. Enrique M. Ostrea, Jr., the leading authority on meconium drug testing has done numerous drug screens to detect methamphetamines in meconium using the Mectest Processor. Should you wish more information of this subject, we strongly suggest that you contact Dr. Ostrea at Hutzel Hospital, Department of Pediatrics in Detroit, Michigan.

Additional information may be obtained from:

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