§40.159 11/03

QUESTION:

What does an MRO do when a drug test result is invalid due to "color discrepancy?"

ANSWER:

- If "Invalid Color difference" is the only result reported to you, you must follow the guidance of §40.159 by contacting the laboratory to obtain more specific information about the color difference between the specimens, and contacting the donor to obtain a legitimate explanation for the color difference. While there is no legitimate medical reason for anyone being able to provide a specimen that separates into two different colors when placed in two different bottles, the interview is necessary to determine appropriate follow-on action.
- You must determine whether the donor has provided you with a legitimate explanation for the color difference (e.g., the collector used two separate voids for the collection), or not (e.g., no clue as to how the colors changed by the time the specimens reached the laboratory).
- You must follow §40.159 for canceling the result, reporting the result to the employer, determining whether a recollection is necessary and, if so, should it be under direct observation.
- If the laboratory has also reported to you that the specimen is positive, adulterated, or substituted, then you must process the results in accordance with §40.129-131. If you determine (i.e., verify) the final result to be positive, adulterated, or substituted, then no additional action is required by you due to the color difference. You must not direct the employee to take another test.
- Notify the employer that the collector must receive "error correction training" as required by §40.33(f). The area of Part 40 in which the collector needs to be retrained is §40.65(a).

QUESTION:

During periods of hot weather, how may Medical Review Officers (MROs) handle laboratory results reported as invalid because of pH greater than or equal to 9.0 but less than or equal to 9.5?

ANSWER:

- Part 40 requires an MRO to provide an employee the opportunity to present a medical explanation for an invalid test result, to include any related to pH.
 - -- If the employee provides an acceptable medical explanation, the MRO is authorized to cancel the test and take no further action.
 - -- If there is no acceptable medical explanation, the MRO will cancel the test and will notify the employer or Designated Employer Representative (DER) to direct another collection under direct observation.
- The Department is aware of current research and studies offering evidence that, over time, heat may cause the pH to rise, typically into the range of 9.0 through 9.3, but not higher than 9.5. [See, for example, "Urine pH: the Effects of Time and Temperature after Collection," Journal of Analytical Toxicology, Vol. 31, October 2007.]
- Consequently, when an employee has no other medical explanation for the pH in the 9.0 9.5 range, MROs should consider whether there is evidence of elapsed time and increased temperature that could account for the pH value.
- In doing so, MROs are authorized to consider the following:
 - -- The temperature conditions that were likely to have existed between the time of collection and transportation of the specimen to the laboratory; and
 - -- The length of time between the specimen collection and arrival at the laboratory.
- MROs may talk with the collection sites to discuss time and temperature issues, including any pertinent information regarding specimen storage.
- If the MRO determines that time and temperature account for the pH value, the MRO is authorized to cancel the test and take no further action.
- If the MRO determines that time and temperature fail to account for the pH value, the MRO is authorized cancel the test and direct another collection under direct observation.