

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  04D2296094	<b>(X3) Date Survey Completed</b>  07/10/2025
<b>Name of Provider or Supplier</b>  Hermes Laboratories	<b>Street Address, City, State</b>  2 Lile Court, Suite 102b, Little Rock, AR	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D5209</b>	<p><b>PERSONNEL COMPETENCY ASSESSMENT POLICIES</b> CFR(s): 493.1235</p> <p>As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency.</p> <p>This STANDARD is not met as evidenced by: Based upon a review of the CMS 209 form, review of laboratory documentation of competency assessment, lack of documentation and interview with laboratory staff the laboratory failed to assess testing personnel competency on an annual basis for two of two testing personnel listed on the CMS 209 form. Findings follow: A) Review of the CMS 209 form revealed that two testing personnel (numbers 2 and 3 on the form CMS 209) were employed by the laboratory. B) Review of competency assessment records revealed that the testing personnel (numbers 2 and 3 on the CMS 209 form) had no record of competency evaluation. C) Upon request, the laboratory was unable to provide competency assessments for testing personnel (numbers 2 and 3 on the CMS 209 form). D) In an interview on 7/10/25 at 9: 15 a.m., the laboratory staff member (# 1 on the separate employee identification list) confirmed that competency assessments for the testing personnel identified above were not performed and the employees had performed testing in the laboratory since the laboratory applied for a certificate of compliance..</p>
<b>D5317</b>	<p><b>SPECIMEN SUBMISSION, HANDLING, AND REFERRAL</b> CFR(s): 493.1242(d)</p> <p>(d) If the laboratory accepts a referral specimen, written instructions must be available to the laboratory's clients and must include, as appropriate, the information specified in paragraphs (a)(1) through (a)(7) of this section.</p>

This STANDARD is not met as evidenced by:  
 Based upon interview and lack of documentation the laboratory did not provide clients with written instructions for specimen submission, handling, and referral as specified in CFR 493.1242 paragraphs (a)(1) through (a)(7). A) In an interview on 7/10/25 at 10:40 a.m.the laboratory staff member (number 2 on the CMS 209 form) stated that all specimens tested in the laboratory are referred from outside clients. B) Upon request, the laboratory could not provide a copy of a client services manual or evidence of instructions for specimen collection and handling that is provided to clients . C) In an interview on 7/10/25 at 10:40 a.m. the laboratory staff member (number 2 on the CMS 209 form) said that the laboratory has been accepting patient samples from outside clients since 6/10/25, has tested thirty patients to date, and they are working on a client specimen manual but haven't completed and distributed one at this time

**D5467**

**CONTROL PROCEDURES**  
 CFR(s): 493.1256(d)(9)(g)

(d)(9) When using calibration material as a control material, use calibration material from a different lot number than that used to establish a cut-off value or to calibrate the test system.

This STANDARD is not met as evidenced by:  
 Based upon review of policy and procedure for "Analysis of Metabolites in Human Urine by LC/MS/MS", and interview with laboratory staff, the laboratory used the same lot number of certified analytical reference materials to prepare both standards and quality control materials for test performance. Findings follow: A) Review of procedures for "Analysis of Metabolites in Human Urine by LC/MS/MS, a "mixed analyte stock solution is prepared by spiking known concentrations of NIST traceable, certified analytical reference materials" from which standards and quality controls are prepared. B) In an interview on 7/10/25 at 09:25 a.m., the laboratory staff member ( number 2 on the form CMS 209) confirmed that standards and quality controls are prepared from the same stock solution at the same time.

**D5779**

**CORRECTIVE ACTIONS**  
 CFR(s): 493.1282(a)

(a) Corrective action policies and procedures must be available and followed as necessary to maintain the laboratory's operation for testing patient specimens in a manner that ensures accurate and reliable patient test results and reports.

This STANDARD is not met as evidenced by:  
 Based upon a review of laboratory policies and procedures, lack of documentation, and interviews with laboratory staff, the laboratory failed to have written policies and procedures for corrective actions when quality control results failed to meet acceptable criteria. Survey findings follow: A) A review of the laboratory general policies and procedures and the Metabolites in Human Urine by LC/MS/MS Policy and Procedure Manual revealed that there were no written policies for corrective actions when quality controls failed to meet the acceptable criteria. B) In an interview at 12:37 p.m.on 7/10/25, laboratory employee #2 (as listed on the form CMS-209) confirmed the lack of written corrective action policies for quality control failures.

**D6107**

**LABORATORY DIRECTOR RESPONSIBILITIES**

CFR(s): 493.1445(e)(15)

(e)(15) Specify, in writing, the responsibilities and duties of each consultant and each supervisor, as well as each person engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or result reporting and whether supervisory or director review is required prior to reporting patient test results.

This STANDARD is not met as evidenced by:

Based upon a review of personnel records for laboratory personnel, lack of documentation, and interviews with laboratory staff, the Laboratory Director failed to specify, in writing, the procedures two of two testing personnel can perform, and whether supervision is required. Survey findings follow: A) Personnel records for clinical laboratory employees #2, #3 as listed on the form CMS-209, failed to include written authorization to perform testing, signed by the laboratory director. B) Upon request, the laboratory was unable to provide written authorization to perform testing for testing personnel (#2 and #3 on form CMS 209). C) In an interview at 10:58 on 7 /10/25 laboratory staff member (#1 on a separate employee identification list) confirmed that lack of signed authorizations for laboratory testing personnel.