

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  44D0313471	<b>(X3) Date Survey Completed</b>  01/12/2023
<b>Name of Provider or Supplier</b>  Rhea Clinic Pc	<b>Street Address, City, State</b>  17310 Hwy 64, Somerville, TN	
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>PERSONNEL COMPETENCY ASSESSMENT POLICIES 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 on review of the laboratory procedure manual, employee personnel records for 2021, 2022, and 2023, and interview with the lead testing person, the laboratory failed to have personnel policies for assessing competency that was in compliance with the regulations in subpart M. The findings include: 1) Review of the laboratory procedure manual and competency assessment documentation forms revealed the following that was not included in the testing personnel competency assessment policy: initial training and demonstration of accuracy semiannual competency during the first year of testing annual competency thereafter assessment of problem solving skills blind testing 2. Review of testing personnel files revealed the following for the Cell Dyn Emerald Complete Blood Count instrument: testing person #1: began patient testing in January 2021, no documentation of initial training with demonstration of accuracy, no blind testing and no problem solving for competency performed in 2021, 2022 and 2023. testing person #2: began patient testing in March 2022, no semiannual competency, no blind testing and no problem solving for competency performed in 2022 and 2023. testing person # 3: began patient testing in August 2021, no documentation of initial training with demonstration of accuracy during training, no annual competency for 2022, no documentation of blind testing or problem solving for competency performed 1/04/2022 and 1/03/2022 . testing person #4: annual competencies performed 8/18/2021, 1/04/2022, and 1/03/2023 did not include documentation of blind testing or problem solving. 3) Interview on January 12, 2023 at 1:25 p.m. with the lead testing person confirmed the testing personnel competency procedure was not in compliance with subpart M of the regulations when it did not</p>

include requirement for initial training and demonstration of accuracy during training, requirement for semiannual competency during the first year of testing, annual competency thereafter and documentation did not include assessment of problem solving skills or blind testing on the competency assessment forms.

**D6053**

**TECHNICAL CONSULTANT RESPONSIBILITIES**  
CFR(s): 493.1413(b)(9)

The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least semiannually during the first year the individual tests patient specimens.

This STANDARD is not met as evidenced by:  
Based on a review of the laboratory's Centers For Medicare and Medicaid Services Laboratory Personnel Report (CLIA) (Form CMS-209), personnel file and an interview with the lead testing person, the Technical Consultant (TC) failed to perform and document semi-annual competency evaluation for 3 of 5 testing personnel in 2021 and 2022. The findings include: 1. Review of the laboratory's Form CMS-209 revealed five testing personnel performing moderate complexity testing. 2. Review of testing personnel files revealed no semi-annual competency evaluation results for the following: testing person #2: began patient testing in January 2021. testing person #3: began patient testing in March 2022. testing person # 4: began patient testing in August 2021. 3. Interview with the lead testing person on January 12, 2023 at 1:25 pm confirmed that no semi-annual competency evaluation performed and documented for three of five testing person in 2021 and 2022.