

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 01D1012367	(X3) Date Survey Completed 10/24/2023
Name of Provider or Supplier Huntsville Reproductive Medicine Pc	Street Address, City, State 20 Hughes Road Sutie 203, Madison, AL	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D2009	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1)</p> <p>The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods.</p> <p>This STANDARD is not met as evidenced by: Based on a review of the American Association of Bioanalysts (AAB) Proficiency Testing (PT) records and an interview with Testing Personnel #1, the laboratory failed to ensure the Laboratory Director signed the attestation statements for five of eight events in 2022. The findings include: 1. A review of the AAB PT records revealed the no signature by the previous Laboratory Director (or designee) on attestation statements for the following surveys: a) 2022 Chemistry Q3. b) 2022 Non-Chemistry Q3. c) 2022 Andrology and Embryology S2. d) 2022 Chemistry Q1. e) 2022 Non-Chemistry Q1. 2. During an interview on October 24, 2023, at 12:17 PM, Testing Personnel #1 confirmed the above findings.</p>
D6053	<p>TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on a review of the personnel records and an interview with Testing Personnel #1, the previous technical consultant failed to ensure all testing personnel had documentation of semi-annual competency assessments. The surveyor noted no</p>

documentation of the 2022 semi-annual competency assessment for four of seven testing personnel listed on the CMS-209 (Laboratory Personnel Report). The findings include: 1. A review of the personnel records revealed Testing Personnel #4-7 initial competency evaluations were performed in 2021 (reviewed during the previous survey) and annual in 2023. There was no documentation of a 2022 semi-annual competency assessment. 2. During an interview on October 24, 2023, at 12:17 PM, Testing Personnel #1 confirmed the above findings.

D6054

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 annually, after the first year.

This STANDARD is not met as evidenced by:
Based on a review of the personnel records and an interview with Testing Personnel #1, the previous technical consultant failed to ensure all testing personnel had documentation of annual competency assessments. The surveyor noted no documentation of the 2022 annual competency assessment for four of seven testing personnel listed on the CMS-209 (Laboratory Personnel Report). The findings include: 1. A review of the personnel records revealed Testing Personnel #4-7 initial competency evaluations were performed in 2021 (reviewed during the previous survey) and annual in 2023. There was no documentation of a 2022 annual competency assessment. 2. During an interview on October 24, 2023, at 12:17 PM, Testing Personnel #1 confirmed the above findings.