

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  21D0220811	<b>(X3) Date Survey Completed</b>  05/16/2024
<b>Name of Provider or Supplier</b>  Hagerstown Reproductive Health Svcs	<b>Street Address, City, State</b>  160 West Washington Street, Hagerstown, MD	
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>D5417</b>	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d)</p> <p>Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality.</p> <p>This STANDARD is not met as evidenced by: Based on review of the Rhesus (Rh) daily quality control (QC) worksheet for the and interview with testing person (TP), the laboratory failed to ensure that the expiration dates of the QC materials used were not used past the expiration date. Findings: 1. The Rh QC worksheet showed that the Mono clonal QC was tested and recorded on 05/14/24 and 05/16/24. The Mono clonal QC used expired on 05/11/2024 and patients were tested and reported. 2. During the survey on 05/17/2024 at 2:10 PM, the TP confirmed that the Mono clonal QC testing on 05/14/24 and 05/16/24 had expired on 05/11/2024.</p>
<b>D5787</b>	<p>TEST RECORDS CFR(s): 493.1283(a)</p> <p>The laboratory must maintain an information or record system that includes the following: (a)(1) The positive identification of the specimen. (a)(2) The date and time of specimen receipt into the laboratory. (a)(3) The condition and disposition of specimens that do not meet the laboratory's criteria for specimen acceptability. (a)(4) The records and dates of all specimen testing, including the identity of the personnel who performed the test(s).</p> <p>This STANDARD is not met as evidenced by: Based on review of the patient and quality control (QC) worksheets for the</p>

immunohematology testing and interview with the testing personnel (TP), the laboratory's record system failed to include the identity of the personnel who performed the patient and quality control testing. Findings: 1. Review of the daily patient worksheets showed that the testing person signed the top of the worksheet. The daily patient worksheet included the test results for hemoglobin, Rhesus (Rh) factor and pregnancy test results. When interviewed the TP confirmed that there are times when one TP performs two of the three tests listed on the worksheet and another TP performs the third test. The daily worksheet only has the name of the person who started the worksheet for that date, but not for anyone else who may perform testing that day. 2. Review of the Rh QC worksheet showed that there were no initials of the person who performed the Rh QC each day of testing. 3. During the survey on 05/16/2024 at 2:00 PM the TP confirmed that the patient and QC worksheets for the immunohematology failed to include the initials of the person who performed the testing.