

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 45D0660286	<b>(X3) Date Survey Completed</b> 10/30/2025
<b>Name of Provider or Supplier</b> Liberty Dayton Regional Medical Center	<b>Street Address, City, State</b> 1353 North Travis Street, Liberty, TX	
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>D0000</b>	An announced survey of the laboratory was conducted on October 29-30, 2025. The laboratory was found out of compliance with the CLIA regulations (42 CFR Part 493, Requirements for Laboratories). The CONDITIONS NOT MET were: D2000 - 42 C. F.R. 493.801 Enrollment And Testing Of Samples
<b>D2000</b>	<p>ENROLLMENT AND TESTING OF SAMPLES CFR(s): 493.801</p> <p>Each laboratory must enroll in a proficiency testing (PT) program that meets the criteria in subpart I of this part and is approved by HHS. The laboratory must enroll in an approved program or programs for each of the specialties and subspecialties for which it seeks certification. The laboratory must test the samples in the same manner as patients' specimens. For laboratories subject to 42 CFR part 493 published on March 14, 1990 (55 FR 9538) prior to September 1, 1992, the rules of this subpart are effective on September 1, 1992. For all other laboratories, the rules of this subpart are effective January 1, 1994.</p> <p>This CONDITION is not met as evidenced by: Based on a review of the laboratory's records and staff interview, the laboratory failed to have documentation of being enrolled in an HHS approved proficiency testing program for the analyte Folate in 2025. Findings include: 1. A review of the laboratory's testing records revealed the laboratory performed Folate testing using patient's serum specimens. 2. A review of the laboratory's records revealed the laboratory failed to provide documentation of enrollment in an HHS approved proficiency testing program for the analyte Folate in 2025. 3. Further review of the laboratory's records revealed the laboratory estimated performing 46 Folate tests using patient's serum specimens annually. 4. In an interview on 10/29/25 at 10:50 a.m. in the conference room, after review of the records, general supervisor #2 (as indicated on the CMS 209 form) confirmed the above findings. Key: HHS= Health and Human Services</p>

## TEST REPORT

CFR(s): 493.1291(c)

(c) The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability.

This STANDARD is not met as evidenced by:

Based on review of laboratory's test menu, manufacturer instructions, random patient reports and staff interview, the laboratory failed to include on the final patient report the test methodology, specimen source/type or date tested/reported for eleven of eleven molecular microbiology by polymerase chain reaction (PCR) analytes tested on the Cepheid GeneXpert XVI test system in 2025. Findings included: 1. Review of laboratory's test menu revealed the laboratory used the following panels for PCR testing/detection of eleven analytes on the Cepheid GeneXpert XVI test system: Xpert CT/GC (Chlamydia/Gonorrhoeae) - designed for detection of presence of Chlamydia trachomatis and Neisseria gonorrhoeae Xpert Xpress CoV-2/Flu/RSV Plus - designed for detection of presence of SARS-Covid19, Influenza A, Influenza B and Respiratory Syncytial Virus (RSV). Xpert Xpress MPV (Multiplex Vaginal Panel) - designed for detection of presence of Bacterial Vaginosis, Candida glabrata/Candida krusei, Candida group and Trichomonas vaginalis Xpert Xpress Strep A (Streptococcus pyogenes) - designed for detection of presence of Streptococcus pyogenes (Group A) 2. Review of manufacturer's instructions revealed the following acceptable specimen types for the above PCR test panels: Xpert CT/GC (document: 2024 Cepheid 5120-02) acceptable specimens: vaginal swabs, endocervical swabs, pharyngeal swabs, rectal swabs, urine. Xpert Xpress CoV-2/Flu/RSV Plus (document: 2023-2024 Cepheid 10073-02) acceptable specimens: nasopharyngeal or anterior nasal swabs. Xpert Xpress MPV (document: 2023 Cepheid 10069-01) acceptable specimens: vaginal swabs. Xpert Xpress Strep A (document: 2023 Cepheid 10070-02) acceptable specimens: throat swabs. 3. Review of random patient reports for the above panels revealed results for Chlamydia trachomatis, Neisseria gonorrhoeae, Influenza A, Influenza B, RSV, Bacterial Vaginosis, Candida glabrata-krusei, Candida group, Trichomonas vaginalis and Streptococcus pyogenes were documented under the header of "Immunology/Serology" test results and did not have specifications that the tests utilized a PCR method of detection (except for Streptococcus pyogenes and SARS-CoV-2). The reports also did not have documentation of specimen source/type, or date tested/reported. The results reviewed were for the following patients: Patient MRN (medical record number): 111572 Sample collected: 10/28/2025 at 08:57 Panel Tested: Xpert Xpress CoV-2/Flu/RSV Plus and Xpert Xpress Strep A No specimen type distinction was documented between the two panels. Patient MRN: 96649 Sample collected: 09/18/2025 at 10:08 Panel Tested: Xpert Xpress MPV and Xpert CT /GC Patient MRN: 529920 Sample collected: 09/30/2025 at 14:06 Panel Tested: Xpert Xpress MPV Patient MRN: 534511 Sample collected: 10/29/2025 at 11:23 Panel Tested: Xpert Xpress CoV-2/Flu/RSV Plus and Xpert Xpress Strep A No specimen type distinction was documented between the two panels. Patient MRN: 93771 Sample collected: 10/24/2025 at 07:43 Panel Tested: Xpert Xpress CoV-2/Flu/RSV Plus and Xpert Xpress Strep A No specimen type distinction was documented

between the two panels. Patient MRN: 530271 Sample collected: 10/25/2025 at 15:01 Panel Tested: Xpert Xpress CoV-2/Flu/RSV Plus and Xpert Xpress Strep A No specimen type distinction was documented between the two panels. Patient MRN: 505868 Sample collected: 10/10/2025 at 12:56 Panel Tested: Xpert CT/GC Patient MRN: 107652 Sample collected: 10/28/2025 at 15:00 Panel Tested: Xpert CT/GC Results for this patient (under one collection date/time) included in the same column results for Hep C Ab (Hepatitis C Antibodies). There was no distinction between the CT/GC and Hep C Ab specimen types or testing methodologies. 4. In an interview on 10/30/2025 at 1200 hours in the conference room, the laboratory's General Supervisor number 1 (as indicated on submitted Form CMS 209) confirmed the findings.