

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  01D0301738	<b>(X3) Date Survey Completed</b>  08/11/2021
<b>Name of Provider or Supplier</b>  University Medical Center	<b>Street Address, City, State</b>  850 Peter Bryce Blvd, Tuscaloosa, AL	
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>D5407</b>	<p>PROCEDURE MANUAL CFR(s): 493.1251(d)</p> <p>Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use.</p> <p>This STANDARD is not met as evidenced by: Based on a review of the Procedure Manual and an interview with the Technical Supervisor #1, the Laboratory Director failed to approve the MedTox Scan Drug of Abuse Test Procedure before patient testing began. The findings include: 1. A review of the MedTox Scan Drug of Abuse Test Procedure revealed the procedure was signed by the current Laboratory Director on 07/28/2020 and patient testing started on 06/16/2020. The current Laboratory Director did not become the Laboratory Director until 09/01/2020. 2. During an interview on 08/11/2021 at 9:15 AM, Technical Supervisor #1 confirmed the above findings.</p>
<b>D5449</b>	<p>CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(ii)(g)</p> <p>Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- At least once a day patient specimens are assayed or examined perform the following for-- Each qualitative procedure, include a negative and positive control material; (g) The laboratory must document all control procedures performed.</p> <p>This STANDARD is not met as evidenced by: Based on a review of MedTox Scan Drugs of Abuse Test and Cepheid Xpert Xpress SARS-CoV-2 quality control, MedTox Scan Drugs of Abuse Test and Cepheid Xpert Xpress SARS-CoV-2 package insert (procedure) and an interview with the Technical</p>

Supervisor #1, the laboratory failed run controls each day patient tests are performed or implement an Individualized Quality Control Plan (IQCP) for MedTox Scan Drugs of Abuse Test and Cepheid Xpert Xpress SARS-CoV-2. This was noted for the MedTox Scan Drugs of Abuse Test from 06/16/2020 when patient testing started to August 2021 (day of survey) and for Cepheid Xpert Xpress SARS-CoV-2 April 2021 when patient testing started to August 2021 (day of survey). The findings include: 1. A review of the quality control for MedTox Scan Drugs of Abuse Test revealed quality control was being performed once a month or new lot/shipment on the following days: 06/09/2020, 07/09/2020, 08/11/2020, 09/21/2020, 10/21/2020, 11/10/2020, 12/10/2020, 01/08/2021, 02/23/2021, 03/08/2021, 04/01/2021, 04/22/2021, 04/23/2021, 05/20/2021, 05/24/2021, 06/17/2021, 07/19/2021, and 07/23/2021. A review of the quality control for Cepheid Xpert Xpress SARS-CoV-2 revealed quality control was being performed once a month or new lot/shipment on the following days: 04/12/2021, 05/03/2021, 05/10/2021, 5/26/2021, 07/08/2021, 08/05/2021, and 08/11/2021. 2. A review of the MedTox Scan Drugs of Abuse Test package insert stated ".... Users should follow government regulations for the running of QC material ... You should run external controls routinely or as needed for any of the following reasons: (1) to practice the test with a know control, (2) when you open a new lot of devices, (3) once a week, (4) if you suspect that the reader or test device is not working properly, (5) if you have had a repeated unexpected test result, or (6) if you suspect that the test devices have been stored improperly." A review of the Cepheid Xpert Xpress SARS-CoV-2 package insert stated "...External controls described in Section 9 are available but not provided and may be used in accordance with local, state, and federal accrediting organizations, as applicable..." 3. During an interview on 08/11/2021 at 3:30 PM, Technical Supervisor #1 confirmed the Laboratory was performing Quality Control every 30 days, new lot, or new shipment and an IQCP had not been written for MedTox Scan Drugs of Abuse Test and Cepheid Xpert Xpress SARS-CoV-2.

**D6120**

**TECHNICAL SUPERVISOR RESPONSIBILITIES**  
 CFR(s): 493.1451(b)(7)(8)

(7) The technical supervisor is responsible for identifying training needs and assuring that each individual performing tests receives regular in-service training and education appropriate for the type and complexity of the laboratory services performed; (8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently.

This STANDARD is not met as evidenced by:  
 Based on a review of the personnel records and an interview with Technical Supervisor #1, the Technical Supervisor failed to provide documentation of initial training for all test systems in the laboratory for Technical Supervisor (TS) #1 and Testing Personnel (TP) #3. This was noted on two out of four laboratory personnel that was new to the laboratory. The finding include: 1. A review of the personnel records revealed the following: a) TS #1 file contained 6-month Competency Assessment completed on 3/04/2020. Initial training was not located during survey. c) TP #3 file contained education documentation, but no initial training was located during the survey; the employee started in March 2021. 2. During an interview conducted on 08/10/2021 at 3:40 PM, Technical Supervisor #1 confirmed the above initial training documentation was done, but documentation could not be located.

**D6128**

**TECHNICAL SUPERVISOR RESPONSIBILITIES**

CFR(s): 493.1451(b)(9)

The technical supervisor is responsible for evaluating and documenting the performance of individuals responsible for high complexity testing at least annually after the first year, unless test methodology or instrumentation changes, in which case, prior to reporting patient test results, the individual's performance must be reevaluated to include the use of the new test methodology or instrumentation.

This STANDARD is not met as evidenced by:

Based on a review of the personnel records and an interview with the Technical Supervisor #1, the Technical Supervisor failed to provide documentation of annual Competency Assessment for all test systems in the laboratory for Technical Supervisor (TS) #1, TS#2, Testing Personnel (TP) #4, TP #5, and TP #6. This was noted for four out of four 2020 Competency Assessments and two out of five 2021 Competency Assessments. The finding include: 1. A review of the personnel records revealed the following: a) TS #1 file contained 6-month Competency Assessment completed on 3/04/2020. Initial training and March 2021 Annual Competency Assessment were not located during survey. b) TS #2 file contained Annual Competency Assessments completed on 06/24/2019 and 03/25/2021. June 2020 Annual Competency Assessment were not located during the survey. c) TP #4 file contained Annual Competency Assessments completed on 06/24/2019 and 03/24/2021. June 2020 Annual Competency Assessment were not located during the survey. d) TP #5 file contained Annual Competency Assessment completed on 06/19/2019. June 2020 and 2021 Annual Competency Assessment were not located during the survey. e) TP #6 file contained Annual Competency Assessments completed on 06/21/2019 and 04/13/2021. June 2020 Annual Competency Assessment were not located during the survey. 2. During an interview conducted on 08/10/2021 at 3:40 PM, Technical Supervisor #1 confirmed the above Competency Assessments were performed, but the documentation could not be located.