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| <b>Statement of Deficiencies</b>   | <b>(X1) Provider/Supplier/CLIA Identification Number</b><br><br>01D0668136         | <b>(X3) Date Survey Completed</b><br><br>06/24/2021 |
| <b>Name of Provider or Supplier</b><br><br>Uahsf Diagnostic Virology Laboratory  | <b>Street Address, City, State</b><br><br>1600 7th Ave S Suite 771, Birmingham, 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>   |
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| <b>D5407</b>              | <p>PROCEDURE MANUAL<br/>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:<br/>Based on a review of the Procedure Manual and an interview with General Supervisor #1, the current Laboratory Director failed to approve Molecular Policy and Procedure Manuals once starting as Laboratory Director and failed to approve procedures for a new test added, before patient testing started. The findings include: 1. A review of the Procedure Manuals revealed that the former Laboratory Director signed the Molecular Policy and Procedure Manual when procedures were put in place, but the current Laboratory Director had not signed these procedures. The current Laboratory Director started at the end of 2019. 2. A review of the Procedure Manuals revealed the Curian HpSA was added May 2020 and signed by General Supervisor #1, but not signed /reviewed by the current Laboratory Director. Patient testing started in June of 2020. 3. A review of the Procedure Manuals revealed the ePlex SARS-CoV-2 Assay Manual was added June 2021 and signed by General Supervisor #1, but not signed/reviewed by the current Laboratory Director. Patient testing started in June of 2020. 4. During an interview on 06/24/2021 at 2:40 PM, General Supervisor #1 confirmed the current Laboratory Director did not approve the Molecular Policy and Procedure Manual upon starting as Laboratory Director. Also, General Supervisor #1 confirmed the Curian HsPA and ePlex SARS-CoV-2 Assay Manual were not approved by the Laboratory Director before patient testing started.</p> |
| <b>D5449</b>              | <p>CONTROL PROCEDURES<br/>CFR(s): 493.1256(d)(3)(ii)(g)</p> <p>Unless CMS Approves a procedure, specified in Appendix C of the State Operations</p>  |

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.

This STANDARD is not met as evidenced by:

Based on a review of Curian HpSA quality control, Curian HpSA package insert (procedure) and an interview with General Supervisor #1, the laboratory failed to perform quality control for Curian HpSA daily (each day of patient testing). This was noted from June 2020, when patient testing started, to June of 2021 (day of survey). The findings include: 1. A review of the quality control for Curian HpSA revealed quality control was being performed weekly starting on 06/24/2020. 2. A review of the Curian HpSA package insert stated "...User should follow the appropriate federal, state, and local guidelines concerning the running of external quality controls." 3. During an interview on 06/24/2021 at 2:40 PM, General Supervisor #1 confirmed the Laboratory was performing Quality Control weekly for the Curian HpSA and an Individualized Quality Control Plan (IQCP) had not been written. General Supervisor #1 stated approximately 600 patient test have been performed since starting this test in June 2020.

**D6106**

**LABORATORY DIRECTOR RESPONSIBILITIES**

CFR(s): 493.1445(e)(14)

The laboratory director must ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process.

This STANDARD is not met as evidenced by:

Based on a review of the Procedure Manual and an interview with the General Supervisor #1, the current Laboratory Director failed to ensure an approved procedure for ePlex SARS-CoV-2 Assay was available before patient testing started. The findings include: 1. A review of the Procedure Manuals revealed the ePlex SARS-CoV-2 Assay Manual was added June 2021 and signed by General Supervisor #1, but not signed/reviewed by the current Laboratory Director. A procedure for this test was not put into place until after a year of patient testing. 2. During an interview on 06/24/2021 at 2:40 PM, General Supervisor #1 confirmed ePlex SARS-CoV-2 Assay Manual were not approved by the Laboratory Director before patient testing started and was not put into place until 06/21/2021.

**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 General Supervisor #1, the Technical Supervisor failed to evaluate and document the

performance of General Supervisor #2 performing Molecular Testing at least annually. This was noted on one of three testing personnel that perform Molecular Testing. The finding include: 1. A review of the personnel records revealed General Supervisor #2 annual evaluation was not documented for 2019 and 2020. The last documented annual evaluation was 11/06/2018. 2. During an interview conducted on 06/24/2021 at 11:00 AM, General Supervisor #1 stated General Supervisor #2 is the Supervisor over Molecular Testing and performs testing in that area. Also, General Supervisor #1 was unaware if the annual evaluations were performed and documented for 2019 and 2020 for General Supervisor #2.