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| Statement of Deficiencies | (X1) Provider/Supplier/CLIA Identification Number 49D0698791 | (X3) Date Survey Completed 07/29/2022 |
| Name of Provider or Supplier Uva Histocompatibility Laboratory | Street Address, City, State North Fork Town Center Four, Charlottesville, VA | |
| 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 |
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| D0000 | An announced CLIA Validation survey was conducted at the UVA Histocompatibility Laboratory on 07/29/22 by the Virginia Department of Health's Office of Licensure and Certification. The laboratory was surveyed under 42 CFR part 493 CLIA Requirements. Specific deficiencies cited are as follows: The laboratory was not in compliance with the following 42 CFR part 493 CLIA Regulations: D6168 - 42 C.F.R. 493-1487 Condition: Testing Personnel. |
| 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 the review of proficiency testing (PT) records, lack of documentation, and interview with the general supervisor, the lab director failed to review and sign eight of 8 attestation statements reviewed. Events of record review include all six events in 2021 and two events in 2022. Findings include: 1. Review of the College of American Pathologists (CAP) PT records revealed the lack of documentation by the lab director for review and signature of the following attestation statements: DML Class I & II Molecular Typing- 2021 events A, B and C; 2022 event A. MX- HLA Crossmatching, Antibody Screen & Antibody Identification- 2021 events A, B and C; 2022 event A. Total of eight events. 2. An exit interview with the general supervisor on 07/29/22 at approximately 2:00 PM confirmed the findings.</p> |
| D6168 | <p>TESTING PERSONNEL CFR(s): 493.1487</p> <p>The laboratory has a sufficient number of individuals who meet the qualification</p> |

requirements of 493.1489 of this subpart to perform the functions specified in 493.1495 of this subpart for the volume and complexity of testing performed.

This CONDITION is not met as evidenced by:

Based on a review of the Laboratory Personnel Report form (CMS 209), available testing personnel records, and interview, the laboratory failed to provide documentation of personnel qualifications for one of six testing personnel responsible for performing and reporting patient test results. Dates of record review: 01/01/21 up to 07/29/22. Refer to D6171.

D6171

TESTING PERSONNEL QUALIFICATIONS

CFR(s): 493.1489(b)

(b) Meet one of the following requirements: (b)(1) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located or have earned a doctoral, master's or bachelor's degree in a chemical, physical, biological or clinical laboratory science, or medical technology from an accredited institution; (b)(2)(i) Have earned an associate degree in a laboratory science, or medical laboratory technology from an accredited institution or-- (b)(2)(ii) Have education and training equivalent to that specified in paragraph (b)(2)(i) of this section that includes-- (b)(2)(ii)(A) At least 60 semester hours, or equivalent, from an accredited institution that, at a minimum, include either-- (b)(2)(ii)(A)(1) 24 semester hours of medical laboratory technology courses; or (b)(2)(ii)(A)(2) 24 semester hours of science courses that include-- (b)(2)(ii)(A)(2)(i) Six semester hours of chemistry; (b)(2)(ii)(A)(2)(ii) Six semester hours of biology; and (b)(2)(ii)(A)(2)(iii) Twelve semester hours of chemistry, biology, or medical laboratory technology in any combination; and (b)(2)(ii)(B) Have laboratory training that includes either of the following: (b)(2)(ii)(B)(1) Completion of a clinical laboratory training program approved or accredited by the ABHES, the CAHEA, or other organization approved by HHS. (This training may be included in the 60 semester hours listed in paragraph (b)(2)(ii)(A) of this section.) (b)(2)(ii)(B)(2) At least 3 months documented laboratory training in each specialty in which the individual performs high complexity testing. (b)(3) Have previously qualified or could have qualified as a technologist under 493.1491 on or before February 28, 1992; (b)(4) On or before April 24, 1995 be a high school graduate or equivalent and have either-- (b)(4)(i) Graduated from a medical laboratory or clinical laboratory training program approved or accredited by ABHES, CAHEA, or other organization approved by HHS; or (b)(4)(ii) Successfully completed an official U.S. military medical laboratory procedures training course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); (b)(5)(i) Until September 1, 1997-- (b)(5)(i)(A) Have earned a high school diploma or equivalent; and (b)(5)(i)(B) Have documentation of training appropriate for the testing performed before analyzing patient specimens. Such training must ensure that the individual has-- (b)(5)(i)(B)(1) The skills required for proper specimen collection, including patient preparation, if applicable, labeling, handling, preservation or fixation, processing or preparation, transportation and storage of specimens; (b)(5)(i)(B)(2) The skills required for implementing all standard laboratory procedures; (b)(5)(i)(B)(3) The skills required for performing each test method and for proper instrument use; (b)(5)(i)(B)(4) The skills required for performing preventive maintenance, troubleshooting, and calibration procedures related to each test performed; (b)(5)(i)(B)(5) A working knowledge of reagent stability and storage; (b)(5)(i)(B)(6) The skills required to implement the quality

control policies and procedures of the laboratory; (b)(5)(i)(B)(7) An awareness of the factors that influence test results; and (b)(5)(i)(B)(8) The skills required to assess and verify the validity of patient test results through the evaluation of quality control values before reporting patient test results; and (b)(5)(i)(B)(8)(ii) As of September 1, 1997, be qualified under 493.1489(b)(1), (b)(2), or (b)(4), except for those individuals qualified under paragraph (b)(5)(i) of this section who were performing high complexity testing on or before April 24, 1995; (b)(6) For blood gas analysis-- (b)(6)(i) Be qualified under 493.1489(b)(1), (b)(2), (b)(3), (b)(4), or (b)(5); (b)(6)(ii) Have earned a bachelor's degree in respiratory therapy or cardiovascular technology from an accredited institution; or (b)(6)(iii) Have earned an associate degree related to pulmonary function from an accredited institution; or (b)(7) For histopathology, meet the qualifications of 493.1449 (b) or (l) to perform tissue examinations.

This STANDARD is not met as evidenced by:

Based on a review of the Laboratory Personnel Report form (CMS 209), available testing personnel records, and an interview, the laboratory failed to provide documentation of personnel qualifications for one of six testing personnel responsible for performing and reporting patient test results at the date of survey on 07/29/22. Dates of record review: 01/01/21 up to 07/29/22. Findings include: 1. Review of the laboratory's CMS 209 form revealed six testing personnel (TP) identified as performing non-waived histocompatibility testing procedures from 01/01/21 up to 07/29/22. 2. Review of the laboratory personnel documents for TP A revealed a statement regarding receipt of a PhD in Organic Chemistry in 1993 from Shanghai Institute of Organic Chemistry Academia Sinicu. The inspector requested to review US equivalent education credentials for TP A. The documentation was not available for review at the date of survey on 07/29/22. 3. An exit interview with the general supervisor on 07/29/22 at approximately 2:00 PM confirmed the findings.