| **Statement of Deficiencies** | **(X1) Provider/Supplier/CLIA Identification Number** | **(X3) Date Survey Completed** |
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| | 49D0222887 | 07/14/2021 |
| **Name of Provider or Supplier** | **Street Address, City, State** | |
| United Medical Laboratories Inc | 1980 Gallows Rd - Suite 300, Vienna, 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 on-site CLIA recertification survey was conducted at United Medical Labs, Inc on July 13, 2021 to July 14, 2021 by the Virginia Department of Health's Office of Licensure and Certification. The survey included remote record review conducted on June 21, 2021 and June 25, 2021. The laboratory was surveyed under 42 CFR part 493 CLIA Regulations. The specific deficiencies are as follows: United Medical Lab Inc is performing SARS CoV-2 (COVID-19) testing and is in compliance with the applicable COVID-19 reporting requirements. |
| **D2004** | ENROLLMENT<br>CFR(s): 493.801(a)(3)<br><br>For each specialty, subspecialty and analyte or test, participate in one approved proficiency testing program or programs, for one year before designating a different program and must notify CMS before any change in designation;<br><br>This STANDARD is not met as evidenced by:<br>Based on review of the laboratory's proficiency testing (PT) records and an interview, the laboratory failed to participate in one (1) approved PT program for Human Chorionic Gonadotropin (HCG) and Thyroid Stimulating Hormone (TSH) for one year before designating a change in PT program in calendar year 2019. Record review was from January 2019 until July 2021. Findings include: 1. Review of the laboratory's PT records revealed the laboratory participated in the following proficiency programs, tests, and events: College of American Pathologists (CAP) - HCG and TSH for 2019 Events 1 and 2; American Association of Bioanalysts (AAB) - HCG and TSH for 2019 Events 2 and 3. 2. An interview with the Technical Supervisor (TS) at approximately 9:45 AM on July 14, 2021, confirmed the findings. The TS stated they switched programs because of the cost of the proficiency module. |
| **D5401** | PROCEDURE MANUAL<br>CFR(s): 493.1251(a) |

A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens.

This STANDARD is not met as evidenced by:
A. Based on the review of the laboratory's policy and procedure manuals, lack of documentation and interviews, the laboratory failed to follow their established policy and document the changing or replacement of the Cytology Stains as defined in the "Gyn Cytology Specimen Processing" procedure for fourteen (14) weeks in 2019 and 14 weeks in 2020. Findings include: 1. Review of the "Gyn Cytology Specimen Processing" procedure (signed by the lab director on July 1, 2014) revealed the following statement: "2. Weekly: All solutions (Xylene, alcohols and ThinPrep stains) should be changed weekly." 2. Review of the laboratory's Cytology logs from February 2019 until October 2020 revealed a lack of documentation of solution change for the following weeks in 2019 and 2020: 2019 May 12-18, 2019; July 28-August 3, 2019; August 4-10, 2019; August 11-17, 2019; August 18-24, 2019; September 1-7, 2019; September 15-21, 2019; October 6-12, 2019; October 20-26, 2019; November 3-9, 2019; November 15-21, 2019; December 1-7, 2019; December 15-21, 2019; and December 22-28, 2019. Total=14 weeks. 2020 January 5-11, 2020; January 12-18, 2020; January 26-February 1, 2020; February 9-15, 2020; February 16-22, 2020; March 1-7, 2020; March 15-21, 2020; May 3-9, 2020; May 24-30, 2020; June 21-27, 2020; July 5-11, 2020; August 9-15, 2020; August 23-29, 2020; and September 13-19, 2020. Total=14 weeks. The surveyor requested documentation of the weekly solution changes for the above listed weeks. The laboratory provided no documentation for review. 3. In an exit interview with the Laboratory Director, Technical Supervisor, General Supervisor, Quality Manager and Administrative Assistant at approximately 12:30 PM on July 14, 2021, the findings were confirmed.
B. Based on the review of the laboratory's policy and procedure manuals, "ThinPrep Stain Solutions Inventory List", lack of documentation and interviews, the laboratory failed to follow their established policy and document when a new set of ThinPrep reagents was received, lot number, open date and the discard date as defined in the "Gyn Cytology Specimen Processing" procedure from March 24, 2020 until July 17, 2020. Findings include: 1. Review of the "Gyn Cytology Specimen Processing" procedure (signed by the lab director on July 1, 2014) revealed the following statement: "When a new set of ThinPrep stain reagents is received, fill out the inventory list with the lot number, open date, and set the discard date to 2 months after the open date. Write down the received and open date on the containers with permanent marker." 2. Review of the laboratory's "ThinPrep Stain Solutions Inventory List" revealed documentation of ThinPrep stain reagents opened on "1/23/20" with discard date of "3/23/20" and "7/17/20" with a discard date of "9/17/20". There was a lack of documentation of the ThinPrep stain reagent's received date, lot number, open date and discard date from 3/24/2020 to 7/16/2020. The surveyor requested documentation of ThinPrep stain reagent's received date, lot number, open date and discard date from 3/24/2020 to 7/16/2020. The laboratory provided no documentation for review. 3. In an exit interview with the Laboratory Director, Technical Supervisor, General Supervisor, Quality Manager and Administrative Assistant at approximately 12:30 PM on July 14, 2021, the findings were confirmed. The laboratory director stated, "I am sure we changed it. We just didn't document it." C. Based on the review of the laboratory's policy and procedure manuals, "ThinPrep 2000 Maintenance Log", lack of documentation and interviews, the laboratory failed to follow their established

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| | policy and document the changing or replacement of the waste tubing every 6 months from January 2019 until October 2020. Findings include: 1. Review of the "Gyn Cytology Specimen Processing" procedure (signed by the lab director on July 1, 2014) revealed the following statement: "Hologic ThinPrep 2000 Machine 4. Every 6 Months: Replace the waste tubing on the side of the machine (refer to the Thin Prep 2000 operating manual for more details." 2. Review of the laboratory's "ThinPrep 2000 Maintenance Log" revealed a lack of documentation of the "Waste Tubing Replacement" from January 2019 until October 2020. The surveyor requested documentation of the every 6 month waste tubing replacement for the ThinPrep 2000 from January 2019 until October 2020. The laboratory provided no documentation to review. 3. In an exit interview with the Laboratory Director, Technical Supervisor, General Supervisor, Quality Manager and Administrative Assistant at approximately 12:30 PM on July 14, 2021, the findings were confirmed. D. Based on the review of the laboratory's policy and procedure manuals, "ThinPrep Image Processor Maintenance Log", lack of documentation and interviews, the laboratory failed to follow their established policy and document the monthly cleaning of the ThinPrep mapping sensor for five (5) of twenty-two (22) months reviewed from January 2019 until October 2020. Findings include: 1. Review of the "Gyn Cytology Specimen Processing" procedure (signed by the lab director on July 1, 2014) revealed the following statement: "Hologic ThinPrep Imaging Machine 1. Monthly: Clean the mapping sensor by wiping the lens with an alcohol prep pad. If their are more errors with the imaging system, it it recommended to clean the map sensor again. " 2. Review of the laboratory's "ThinPrep Image Processor Log" from January 2019 until Octorber 2020 (a total of 22 months) revealed a lack of documentation of the "Cleaning Mapping Sensor" for the following months: April 2019, August 2019, May 2020, July 2020 and September 2020. A total of 5 months. The surveyor requested documentation of the monthly mapping sensor cleaning for the ThinPrep Imaging Processor for April 2019, August 2019, May 2020, July 2020 and September 2020. The laboratory provided no documentation to review. 3. In an exit interview with the Laboratory Director, Technical Supervisor, General Supervisor, Quality Manager and Administrative Assistant at approximately 12:30 PM on July 14, 2021, the findings were confirmed. |
| **D6121** | TECHNICAL SUPERVISOR RESPONSIBILITIES<br>CFR(s): 493.1451(b)(8)(i)<br><br>The procedures for evaluation of the competency of the staff must include, but are not limited to direct observations of routine patient test performance, including patient preparation, if applicable, specimen handling, processing and testing.<br><br>This STANDARD is not met as evidenced by:<br>A. Based on a review of the Centers for Medicare and Medicaid Services (CMS) Laboratory Personnel Report form (CMS 209), laboratory personnel files, lack of documentation, and interviews, the technical supervisor (TS) failed to document competency assessments that included direct observation of high complexity histopathology grossing for two (2) of 2 testing personnel (TP) who perform histopathology grossing in 2020. Findings include: 1. Review of the CMS 209 form revealed 2 TP (TP #1 and #2) were indicated as responsible for the high complexity testing. (See Personnel Code Sheet.) 2. Review of the laboratory personnel files revealed that TP #1 and #2 performed high complexity histopathology grossing. 3. Review of personnel files revealed the laboratory's 2020 competencies for TP #1 and #2 lacked documentation of the required competency element of direct observation of |

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| | routine patient histology grossing for TP #1 and #2. The surveyor requested to review additional competency documentation of direct observation of histopathology grossing. The laboratory provided no documentation for review. 4. In an exit interview with the Laboratory Director, Technical Supervisor, General Supervisor, Quality Manager and Administrative Assistant at approximately 12:30 PM on July 14, 2021, the findings were confirmed. B. Based on a review of the Centers for Medicare and Medicaid Services (CMS) Laboratory Personnel Report form (CMS 209), laboratory personnel files, lack of documentation, and interviews, the technical supervisor (TS) failed to document competency assessments that included direct observation of Chemistry and Hematology testing for 2 of 2 testing personnel (TP) who performed Hematology and Chemistry testing in 2019 and 2020. Findings include: 1. Review of the CMS 209 form revealed 2 TP (TP #3 and TP #4) was indicated as responsible for the high complexity testing. (See Personnel Code Sheet.) 2. Review of the laboratory personnel files revealed that TP #3 was trained to perform testing in Chemistry and Hematology. 3. Review of laboratory personnel files revealed the laboratory's 2019 and 2020 competencies lacked documentation of the required competency element of direct observation of routine patient Hematology and Chemistry testing for TP #3 and TP #4. The surveyor requested to review additional competency documentation of direct observation of Chemistry and Hematology testing for TP #3 and TP #4. The laboratory provided no documentation for review. 4. In an exit interview with the Laboratory Director, Technical Supervisor, General Supervisor, Quality Manager and Administrative Assistant at approximately 12:30 PM on July 14, 2021, the findings were confirmed. |
| **D6122** | TECHNICAL SUPERVISOR RESPONSIBILITIES<br>CFR(s): 493.1451(b)(8)(ii)<br><br>The procedures for evaluation of the competency of the staff must include, but are not limited to monitoring the recording and reporting of test results.<br><br>This STANDARD is not met as evidenced by:<br>A. Based on a review of the Centers for Medicare and Medicaid Services (CMS) Laboratory Personnel Report form (CMS 209), laboratory personnel files, lack of documentation, and interviews, the technical supervisor (TS) failed to document competency assessments that included monitoring the recording and reporting of test restults for high complexity histopathology grossing for two (2) of 2 testing personnel (TP #1 and #2) who performed histopathology grossing in 2020 (see D6121 A). B. Based on a review of the Centers for Medicare and Medicaid Services (CMS) Laboratory Personnel Report form (CMS 209), laboratory personnel files, lack of documentation, and interviews, the technical supervisor (TS) failed to document competency assessments that included monitoring the recording and reporting of test restults of Chemistry and Hematology testing for 2 of 2 testing personnel (TP # 3 and #4) who performed Hematology and Chemistry testing in 2019 and 2020 (See D6121 B). |
| **D6123** | TECHNICAL SUPERVISOR RESPONSIBILITIES<br>CFR(s): 493.1451(b)(8)(iii)<br><br>The procedures for evaluation of the competency of the staff must include, but are not limited to review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventive maintenance records. |

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| | This STANDARD is not met as evidenced by:<br>A. Based on a review of the Centers for Medicare and Medicaid Services (CMS) Laboratory Personnel Report form (CMS 209), laboratory personnel files, lack of documentation, and interviews, the technical supervisor (TS) failed to document competency assessments that included the review of preventative maintenance records for instruments used for high complexity histopathology for two (2) of 2 testing personnel (TP #1 and #2) who performed histopathology grossing in 2020 (see D 6121 A). B. Based on a review of the Centers for Medicare and Medicaid Services (CMS) Laboratory Personnel Report form (CMS 209), laboratory personnel files, lack of documentation, and interviews, the technical supervisor (TS) failed to document competency assessments that included the review of quality control records, proficiency testing results and preventative maintenance records for Chemistry and Hematology testing for 2 of 2 testing personnel (TP #3 and #4) who performed Hematology and Chemistry testing in 2019 and 2020. (see D6121 B). |
| **D6124** | TECHNICAL SUPERVISOR RESPONSIBILITIES<br>CFR(s): 493.1451(b)(8)(iv)<br><br>The procedures for evaluation of the competency of the staff must include, but are not limited to direct observation of performance of instrument maintenance and function checks.<br><br>This STANDARD is not met as evidenced by:<br>A. Based on a review of the Centers for Medicare and Medicaid Services (CMS) Laboratory Personnel Report form (CMS 209), laboratory personnel files, lack of documentation, and interviews, the technical supervisor (TS) failed to document competency assessments that included the direct observation of instrument maintenance and function checks for instruments used for histopathology for two (2) of 2 testing personnel (TP #1 and #2) who performed histopathology grossing in 2020 (see D6121 A). B. Based on a review of the Centers for Medicare and Medicaid Services (CMS) Laboratory Personnel Report form (CMS 209), laboratory personnel files, lack of documentation, and interviews, the technical supervisor (TS) failed to document competency assessments that included the direct observation of instrument maintenance and function checks for instruments used for Chemistry and Hematology testing for 2 of 2 testing personnel (TP #3 and #4) who performed Hematology and Chemistry testing in 2019 and 2020 (see D6121 B). |
| **D6125** | TECHNICAL SUPERVISOR RESPONSIBILITIES<br>CFR(s): 493.1451(b)(8)(v)<br><br>The procedures for evaluation of the competency of the staff must include, but are not limited to assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples.<br><br>This STANDARD is not met as evidenced by:<br>A. Based on a review of the Centers for Medicare and Medicaid Services (CMS) Laboratory Personnel Report form (CMS 209), laboratory personnel files, lack of documentation, and interviews, the technical supervisor (TS) failed to document competency assessments that included the assessment of test performance using blind samples in histopathology for two (2) of 2 testing personnel (TP #1 and #2) who |

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| | performed histopathology grossing in 2020 (see D6121 A). B. Based on a review of the Centers for Medicare and Medicaid Services (CMS) Laboratory Personnel Report form (CMS 209), laboratory personnel files, lack of documentation, and interviews, the technical supervisor (TS) failed to document competency assessments that included the assessment of test performance using previously analyzed specimens, internal blind samples or external proficiency testing samples in Chemistry and Hematology testing for 2 of 2 testing personnel (TP #3 and #4) who performed Hematology and Chemistry testing in 2019 and 2020 (see D6121 B). |