| **Statement of Deficiencies** | **(X1) Provider/Supplier/CLIA Identification Number** | **(X3) Date Survey Completed** |
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| | 49D0226718 | 11/20/2018 |
| **Name of Provider or Supplier** | **Street Address, City, State** | |
| Drs Titus Hendrix Turner Pahle And | 2201 Grove Avenue, Richmond, 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 recertification survey was conducted at the lab of Dr.'s Titus, Hendrix, Turner, Pahle, and Christiansen on November 20, 2018 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: |
| **D2015** | TESTING OF PROFICIENCY TESTING SAMPLES<br>CFR(s): 493.801(b)(5)(6)<br><br>(5) The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the proficiency testing event. (6) PT is required for only the test system, assay, or examination used as the primary method for patient testing during the PT event.<br><br>This STANDARD is not met as evidenced by:<br>Based on a review of the laboratory's proficiency testing (PT) documentation, and an interview, the laboratory failed to retain instrument result print outs and attestation statements signed by the laboratory director (LD) and testing personnel (TP) for one (1) of six (6) hematology events reviewed. **REPEAT DEFICIENCY Findings include: 1. Review of the laboratory's 2017 and 2018 Medical Laboratory Evaluation (MLE) hematology PT documentation, a total of 6 events, revealed no Beckman Coulter ACTdiff complete blood count instrument print outs or signed attestation statements for the 2017 Event M2. The inspector requested to review: ACTdiff instrument print outs for the five (5) PT samples resulted (HD 6, HD 7, HD 8, HD 9, |

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| | and HD 10) and the LD and TP attestation documentation. No documentation was available for review. 2. In an interview with the primary TP and LD at approximately 1:00 PM, it was confirmed that the laboratory failed to retain copies of the instrument PT results and attestation statements as outlined above. |
| **D5203** | SPECIMEN IDENTIFICATION AND INTEGRITY<br>CFR(s): 493.1232<br><br>The laboratory must establish and follow written policies and procedures that ensure positive identification and optimum integrity of a patient's specimen from the time of collection or receipt of the specimen through completion of testing and reporting of results.<br><br>This STANDARD is not met as evidenced by:<br>Based on a tour, review of the laboratory's policies and procedures, and interviews, the laboratory failed to follow their policy for labeling patient samples using two (2) patient identifiers on eight (8) of 8 urine samples, observed in the sample processing area, on November 20, 2018. Findings include: 1. During a tour with the primary testing personnel, at approximately 11:30 AM, the inspector observed 8 patient urine samples in the laboratory's urine processing area: One (1) urine sample was labeled with patient first and last name; Three (3) urine samples were labeled with patient last name, first initial; Four (4) urine samples were labeled with patient last name; The inspector asked the primary testing personnel (TP) to describe the process of labeling patient urine samples. The TP stated: "our policy requests that the patient's full name be on the urine cup. We have our patients write their names on the cups. We label our urine centrifuge tubes according to the cup label and place at microscope". 2. Review of the policies and procedure manual revealed a quality assurance (QA) procedure that stated: "patient samples will be labeled with two unique identifiers throughout the testing process". 3. In an interview with the primary testing personnel and lab director at approximately 1:00 PM, it was confirmed that the laboratory failed to follow their policy to ensure two (2) unique identifiers were placed on patient samples on November 20, 2018 as outlined above. |
| **D5217** | EVALUATION OF PROFICIENCY TESTING PERFORMANCE<br>CFR(s): 493.1236(c)(1)<br><br>At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part.<br><br>This STANDARD is not met as evidenced by:<br>Based on a review of test logs, available proficiency testing (PT) records, and an interview, the laboratory failed to perform split sample comparisons or accuracy verification two (2) times per year for urine sediment microscopy in the twenty-four (24) months reviewed. Findings include: 1. Review of the laboratory's test logs revealed that three (3) testing personnel (TP) performed urine sediment microscopy examination in the laboratory from January 2017 to the date of the inspection on 11/20 /2018. 2. Review of the laboratory's PT records for 2017 and 2018 revealed no enrollment or participation with Medical Laboratory Evaluation PT, split sample comparisons, or other documentation of accuracy verification for urine sediment microscopy results for TP A, B, or C. (See TP Code Sheet attached.) The inspector requested documentation of split sample comparison or accuracy verification |

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| | documentation in calendar years 2017 and 2018. No documentation was available for review. 3. In an interview with the primary TP and lab director at approximately 1:00 PM, it was confirmed that the laboratory failed to perform a split sample comparison or accuracy verification two (2) times per year for urine sediment microscopy in the 24 months reviewed. |
| **D5400** | ANALYTIC SYSTEMS<br>CFR(s): 493.1250<br><br>Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in 493.1251 through 493.1283, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub.7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the analytic systems and correct identified problems as specified in 493.1289 for each specialty and subspecialty of testing performed.<br><br>This CONDITION is not met as evidenced by:<br>Based on a review of the laboratory's policies and procedures, temperature and maintenance logs, manufacturer's package inserts, operators manual, and interviews, it was determined that the laboratory failed to: 1. ensure that Beckman Coulter manufacturer's instructions were followed for the storage and stability of 4C-ES Cell complete blood count quality control materials on one hundred five (105) days of the twenty-four (24) months reviewed (Cross Reference D 5411); 2. ensure that opened hematology Beckman Coulter 4C-ES Cell Controls materials were not used beyond the manufacturer's expiration date or when the reagent had deteriorated (Cross Reference D 5417); 3. document periodic maintenance checks of the LW Scientific Ultra Centrifuge used to prepare urine sediment for microscopic examination in the 24 months reviewed (Cross Reference D 5431). |
| **D5411** | TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT<br>CFR(s): 493.1252(a)<br><br>Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253.<br><br>This STANDARD is not met as evidenced by:<br>Based on a review of policies and procedures, temperature logs, manufacturer's package insert, and an interview, the laboratory failed to follow Beckman Coulter's storage and stability instructions for hematology quality control (QC) materials on one hundred five (105) days in the twenty-four (24) months reviewed. Findings include: 1. Review of the policy and procedure manual revealed a quality assurance (QA) policy that stated: "Record daily the temperature of the room, refrigerator, freezer on temperature charts to ensure within range and record corrective actions. The laboratory will follow manufacturer's instructions for storage of reagents". 2. Review of the daily reagent refrigerator temperature logs from January 2, 2017 up to the date of survey on November 20, 2018 revealed the acceptable temperature range to be 2.0 to 8.0 degrees Celsius (C). The inspector noted the following refrigerator temperatures were recorded out of the stated acceptable range in calendar year 2017: April : 04/07 /17 (9.0 C), 04/10/17 (8.5 C), 04/11/17 (8.7 C), 04/12/17 (9.0 C), 04/13/17 (8.8 C), 04 |

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| | /14/17 ( 8.7 C), 04/18/17 (9.6 C), 04/19/17 (9.7 C), 04/20/17 (10.7 C), 04/21/17 (9.5 C), 04/23/17 (9.5 C), 04/26/17 (9.5 C), 04/27/17 (10.5 C), 04/28/17 (9.0 C); May: 05 /02/17 (9.0 C), 05/03/17 (9.4 C), 05/04/17 (8.9 C), 05/05/17 (8.5 C), 05/08/17 (9.6 C), 05/09/17 (8.3 C), 05/10/17 (9.0 C), 05/11/17 (8.5 C), 05/14/17 (9.3 C), 05/15/17 (10.2 C), 05/16/17 (8.8 C), 05/17/17 (9.7 C), 05/18/17 (8.9 C), 05/18/17( 9.5 C), 05/22/17 (8.2 C), 05/23/17 (8.4 C), 05/24/17 (9.2 C), 05/25/17 (8.5 C), 05/26/17 (9.4 C), 05/30 /17 (8.9 C), 05/31/17 ( 9.1 C); June: 06/01/17 (9.3 C), 06/02/17 (8.2. C), 06/05/17 (8.2 C), 06/06/17 ( 9.2 C), 06/07/17 (9.3 C), 06/08/17 (8.3 C), 06/14/17( 9.9 C), 06/15/17 (9.7 C), 06/20/17 (9.8 C), 06/28/17 (9.8 C), 06/29/17 (9.8 C), 06/30/17 (8.7 C); July: 07/03/17 (8.7 C), 07/05/17 (8.7 C), 07/06/17 (9.6 C), 07/07/17 ( 9.2 C), 07/14/17 (9.0 C), 07/17/17 (9.4 C), 07/28/17 (9.4 C), 07/31/17 (9.6 C); August: 08/02/17 (8.8 C), 08 /03/17 (10.4 C), 08/08/17 (9.3 C), 08/09/17 (8.5 C), 08/10/17 (8.4 C), 08/11/17 ( 8.4 C), 08/16/17 (8.6 C), 08/18/17 (8.5 C), 08/22/17 (9.3 C), 08/23/17 (8.5 C), 08/24/17 (9.7 C), 08/25/17 (8.8 C), 08/28/17 (10.4 C), 08/29/17 (8.6 C); September : 09/07/17 (9.1 C), 09/09/17 (9.2 C), 09/11/17 (9.2 C), 09/12/17 (10.5 C), 09/13/17 (9.1 C), 09/14 /17 ( 8.9 C), 09/19/17 (8.6 C), 09/20/17 (9.0 C), 09/25/17 (8.7 C), 09/26/17 (8.6 C); October: 10/03/17 ( 9.1 C) ,10/04/17 (9.5 C), 10/05/17 (9.5 C), 10/06/17 (9.5 C), 10/10 /17 (8.8 C), 10/12/18 ( 8.6 C); November: 11/01/17 ( 9.2 C); December: 12/01/17 (9.4 C), 12/06/17 (8.7 C), 12/11/17 (8.9 C), 12/29/17 (8.5 C), 12/30/17 (9.0 C); A total of ninety-one (91) days. The inspector noted the following refrigerator temperatures were recorded out of the stated acceptable range from January 2, 2018 to November 20, 2018: January: 01/17/18 (8.6 C), 01/19/18 (8.2 C), 01/23/18 (9.3 C), 01/24/18 (9.2 C), 01/25/18 (8.7 C), 01/26/18 (8.7 C); March: 03/20/18 (8.4 C); April : 04/06/18 (8.8 C), 4/10/18 (9.4 C), 4/11/18 (9.6 C); May: 05/10/18 (1.5 C), 05/17/18 (1.5 C); June: 06 /09/18 (1.8 C), 06/12/18 (1.0 C); A total of fourteen (14) days. 3. Review of the Beckman Coulter's 4C-ES Cell Controls package insert revealed instructions that stated: "store the quality control vials at 2 -8 C". 4. In an interview with the primary testing personnel and lab director at approximately 1:00 PM, it was confirmed that the laboratory failed to ensure that Beckman Coulter manufacturer's instructions were followed for the storage and stability of hematology QC materials on 105 days, as outlined above, during the 24 months reviewed. |
| **D5417** | TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT<br>CFR(s): 493.1252(d)<br><br>Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality.<br><br>This STANDARD is not met as evidenced by:<br>Based on a laboratory tour, review of package insert, and an interview, the laboratory failed to ensure that three (3) of 3 opened hematology quality control (QC) vials in use to monitor patient Complete Blood Count (CBC) accuracy and precision were within the manufacturer's expiration date and of standard quality. Findings include: 1. During a laboratory tour at approximately 11:30 AM, it was noted that three (3) vials of Coulter 4C-ES Cell Controls were opened and stored in the refrigerator. The open vials were Level Low, Normal, High (Lot Number 088200). The inspector inquired if the opened vials were in use for monitoring the Beckman Coulter ACTdiff analyzer for CBC testing. The primary testing personnel (TP) confirmed the open vials of Lot 088200 were in use. It was noted by the inspector that one (1) of the 3 vials had signs of deterioration. The inspector inquired how long the 3 vials had been opened for use and what the protocol was for labeling opened control vials to ensure the material was |

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| | within expiration date. The primary TP stated: " I am not sure why the vials were not dated'. The inspector asked if the lab could confirm how long the 3 QC vials had been opened and in use. The TP could not confirm. 2. Review of the Beckman Coulter 4C-ES package insert revealed stability and storage instructions that stated: "Opened tubes are stable for a maximum of twenty run times within 35 days provided they are handled properly. Do not use product if deterioration is suspected. Important information regarding the 4C-ES Cell Control's open vial stability defines the maximum number of events that can occur with each vial. An event occurs each time a vial is taken out of the refrigerator, warmed, and refrigerated again". 3. In an interview with the primary TP and lab director at approximately 1:00 PM, it was confirmed that the laboratory failed to ensure that the hematology control materials listed above were not used beyond the expiration dates or when the reagent had deteriorated. |
| **D5431** | MAINTENANCE AND FUNCTION CHECKS<br>CFR(s): 493.1254(a)(2)<br><br>For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document function checks as defined by the manufacturer and with at least the frequency specified by the manufacturer. Function checks must be within the manufacturer's established limits before patient testing is conducted.<br><br>This STANDARD is not met as evidenced by:<br>Based on a tour, review of maintenance records, manufacturer's operations manual, and an interview, the laboratory failed to document periodic maintenance checks of the urine centrifuge in the twenty-four (24) months reviewed. Findings include: 1. During a tour of the laboratory, at approximately 11:30 AM, the inspector noted a LW Scientific Ultra 8 centrifuge in use for urine microscopic sediment preparation. The inspection calibration label was noted performed on 4/1/13 and verification of 1910 revolutions per minute (RPM) by H & M Sales and Service, INC. The inspector asked the primary testing personnel (TP) to describe the laboratory's policy on equipment maintenance. The TP stated that "we have service come in to do maintenance each year on the microscope, centrifuges, and lab machines". 2. Review of the laboratory's equipment maintenance logs from November 2016 to the date of the survey on 11/20 /18, revealed no RPM calibration or verification documented for the LW Scientific urine centrifuge. The inspector requested to review the calibration records. No documentation was available for review. 3. Review of the LW Scientific Ultra Centrifuge operations manual revealed manufacturer's specifications to "perform urine procedures at the recommended speed of 1800 RPM". The manufacturer's manual stated: "please use a tachometer for calibrating and verification of the RPM's routinely". 4. In an interview with the primary TP and lab director at approximately 1: 00 PM, it was confirmed that the laboratory had failed to periodically document a check or calibration of the RPM's for the LW Scientific urine centrifuge during the 24 months reviewed as outlined above. |
| **D5785** | CORRECTIVE ACTIONS<br>CFR(s): 493.1282(b)(3)<br><br>(b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(3) The criteria for proper storage of reagents and specimens, as specified under 493.1252(b), are not met. |

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| | This STANDARD is not met as evidenced by:<br>Based on a review of policies and procedures, temperature logs, manufacturer's package insert, and an interview, the laboratory failed to document corrective actions taken when refrigerator temperatures exceeded the acceptable range on one hundred five (105) days during the twenty-four (24) months reviewed. **REPEAT DEFICIENCY Findings include: 1. Review of the policy and procedure manual revealed a quality assurance (QA) policy that stated: "Record daily the temperature of the room, refrigerator, freezer on temperature charts to ensure within range and record corrective actions. The laboratory will follow manufacturer's instructions for storage of reagents". 2. Review of the daily reagent refrigerator temperature logs from January 2, 2017 up to the date of survey on November 20, 2018 revealed an acceptable range to be 2.0 to 8.0 degrees Celsius (C) and that recorded temperatures exceeded the range on ninety-one (91) days in calendar year 2017, and fourteen (14) days year to date in 2018. (Cross reference D 5411.) The inspector inquired of the primary testing personnel (TP), at approximately 11:30 AM, if there was documentation of corrective action for the dates when the refrigerator temperatures were out of range. The TP stated: "When the temperatures are out of range we sometimes recheck it later in the day but we do not write anything down to show that we recheck it". 3. Review of the Beckman Coulter's 4C-ES Cell Controls package insert revealed instructions that stated: "store the quality control vials at 2 -8 C". 4. In an interview with the primary testing personnel and lab director at approximately 1:00 PM, it was confirmed that the laboratory failed to document corrective action when temperatures exceeded acceptable ranges, as outlined above, during the 24 months reviewed. |
| **D6000** | MODERATE COMPLEXITY LABORATORY DIRECTOR<br>CFR(s): 493.1403<br><br>The laboratory must have a director who meets the qualification requirements of 493. 1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart.<br><br>This CONDITION is not met as evidenced by:<br>Based on a review of the laboratory's policies, personnel records, and interviews, the laboratory director failed ensure that the competency assessment policy was followed for three (3) of 3 testing personnel in the twenty-four (24) months reviewed. (Cross reference D 6054 -REPEAT DEFICIENCY). |
| **D6054** | TECHNICAL CONSULTANT RESPONSIBILITIES<br>CFR(s): 493.1413(b)(9)<br><br>The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least annually, after the first year.<br><br>This STANDARD is not met as evidenced by:<br>Based on a review of Centers for Medicare and Medicaid Services Laboratory Personnel Report form (CMS 209), laboratory personnel files, policies and procedures, and interview, the technical consultant (TC) failed to perform annual competency evaluations for three (3) of 3 testing personnel in the review timeframe |

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| | from November 2016 to November 2018. **REPEAT DEFICIENCY Findings include: 1. Review of the CMS 209 form revealed that the laboratory director (LD) also performs the duties of TC and that there are 3 testing personnel. 2. Review of the laboratory personnel files revealed that testing personnel A, B, and C lacked an annual competency evaluation in calendar year 2017 and up to the date of the inspection on 11 /20/18. The inspector requested to review competency documentation. No records were available for review. (See attached Personnel Code Sheet.) 3. Review of the policies and procedures revealed a quality assurance (QA) policy that stated: "testing personnel will be assessed annually for competency". 4. In an interview with the primary testing personnel and LD at approximately 1:00 PM, it was confirmed that the TC failed to perform annual competency evaluations for 3 of 3 testing personnel during the twenty-four (24) months reviewed. |