

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 21D2076584	(X3) Date Survey Completed 04/27/2023
Name of Provider or Supplier Capital Diagnostics	Street Address, City, State 14201 Park Center Drive Ste 403, 405 & 407, Laurel, MD	
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
D2015	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(5)(6)</p> <p>(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.</p> <p>This STANDARD is not met as evidenced by: Based on review of proficiency testing (PT) records and interview with the laboratory director (LD) and testing personnel (TP), the laboratory failed to print, sign, and retain the attestation statements according to the instructions of the PT provider for virology and toxicology testing. Findings: 1. The laboratory was enrolled in virology and toxicology PT with College of American Pathologists (CAP). 2. Instructions on the CAP Attestation Statement stated that the laboratory "may use the attestation page provided in the kit instructions or, alternatively, print, sign, and retain a copy of this page for your records and inspection purposes." 3. The virology PT records for 2021-2023 were reviewed for a total of five PT events. The Attestation Statement was printed for two of five reviewed PT events with the LD's and TP's name typed onto the form, but not signed. 4. The Attestation Statement was not printed, signed, and maintained with the virology PT records for three of five reviewed PT events. 5. The toxicology PT records from 2022 and 2023 (four events) were reviewed. The PT attestation worksheets showed that the name of the TP and LD were typed onto the</p>

report and printed but there were no signatures of the TP and LD or designee on the printed report. 6. During the survey on 04/27/2023 at 4:30 PM, the LD and TP confirmed that the CAP Attestation Statements were not printed, signed, and retained according to the CAP instructions.

D5413

TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT
CFR(s): 493.1252(b)

The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.

This STANDARD is not met as evidenced by:
Based on observation, review of the procedure, review of temperature records, and interview with the testing person (TP), the laboratory failed to monitor humidity and room temperature in all rooms where polymerase chain reaction (PCR) testing was performed. Findings: 1. The laboratory had a central laboratory space where multiple PCR instruments were located and three smaller spaces where automated nucleic acid extraction instruments and two biological safety cabinets (BSCs) were located. 2. The laboratory's "Daily Quality Control and Preventative Maintenance" procedure stated to "Record the humidity % from the digital humidity reader. Record data on appropriate maintenance logs." 3. Temperature records showed that the room temperature was being monitored in the central laboratory space containing the multiple PCR instruments, but not in the three smaller spaces containing the extraction instruments and BSCs. 4. There were no records indicating that humidity was being monitored in any of the spaces. 5. During the survey on 04/27/2023 at 11:30 AM, the TP confirmed that room temperature was only being monitored in the central laboratory space and humidity was not being monitored.

D5417

TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT
CFR(s): 493.1252(d)

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.

This STANDARD is not met as evidenced by:
Based on record review and interview with the testing person (TP), the laboratory failed to document the lot numbers, expiration dates, and dates in use for reagents used for performing virology polymerase chain reaction (PCR) testing. Findings: 1. The laboratory used manufacturer's reagents for the extraction and amplification procedures for virology PCR testing. 2. The laboratory had a "QC Lot Tracking" log for the quality control (QC) reagents that documented the date, lot number, expiration date, instrument name, and whether the new QC lot passed verification, but didn't state when each lot number was put into use. 3. There was no documentation of the lot numbers and expiration dates of extraction and amplification reagents and when they were put into use. 4. During the survey on 04/27/2023 at 2:00 PM, the TP confirmed

that the laboratory was not documenting the lot numbers, expiration dates, and dates in use for the reagents used in the extraction and amplification procedures for virology PCR testing.

D5423

ESTABLISHMENT AND VERIFICATION OF PERFORMANCE
CFR(s): 493.1253(b)(2)

Each laboratory that modifies an FDA-cleared or approved test system, or introduces a test system not subject to FDA clearance or approval (including methods developed in-house and standardized methods such as text book procedures), or uses a test system in which performance specifications are not provided by the manufacturer must, before reporting patient test results, establish for each test system the performance specifications for the following performance characteristics, as applicable: (2)(i) Accuracy. (2)(ii) Precision. (2)(iii) Analytical sensitivity. (2)(iv) Analytical specificity to include interfering substances. (2)(v) Reportable range of test results for the test system. (2)(vi) Reference intervals (normal values). (2)(vii) Any other performance characteristic required for test performance.

This STANDARD is not met as evidenced by:

I. Based on review of the validation summaries and interview with the laboratory director (LD), the laboratory failed to evaluate performance specifications for all gene targets for virology polymerase chain reaction (PCR) testing. Findings: 1. The laboratory used the PerkinElmer New Coronavirus Nucleic Acid Detection Kit which identified three targets: the viral nucleocapsid (N) gene, the viral open reading frame 1ab gene (ORF1ab), and bacteriophage MS2 which was spiked into each sample as an internal control (IC). 2. The laboratory had validation summaries for the evaluation of precision, accuracy, specificity, and sensitivity for four instruments approved by the LD on 07/2020, 12/08/2021, 12/23/2021, and 01/08/2022. 3. The summaries only documented the evaluation of results for the ORF1ab gene and did not address the N gene or the IC. 4. During the survey on 04/27/2023 at 4:30 PM, the LD confirmed that the validation summaries only included data to evaluate the ORF1ab gene and not the N gene or the IC. II. Based on review of the validation summaries and interview with the testing person (TP), the laboratory failed to evaluate performance specifications for the internal control (IC) and failed to correlate results for severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) between two reverse transcription polymerase chain reaction (RT-PCR) assay kits as stated in the validation cover sheet. Findings: 1. The laboratory began using the PerkinElmer PKamp Respiratory SARS-CoV-2 RT-PCR Panel 1 assay for detection of SARS-CoV-2, influenza A (Flu A), influenza B (Flu B), and respiratory syncytial virus (RSV) in 01/2023. 2. The assay also detected the human gene RNase P as an IC to monitor sample collection of human biological material and extraction efficiency. 3. The validation cover sheet titled "Capital Diagnostics Implementation Final Approval" (cover sheet) stated that for SARS-CoV-2 results a "Minimum of 5 Positive and 5 Negative patient correlation samples to be correlated against the PerkinElmer New Coronavirus Nucleic Acid Detection Kit." 4. Validation summaries showed that precision, accuracy, specificity, and sensitivity were evaluated for SARS-CoV-2, Flu A, Flu B, and RSV on two PCR instruments. There was no procedure describing what material was used for positive and negative samples. The TP stated that the manufacturer's positive and negative control material was used. 5. There was no data evaluating results for the RNase P IC as no clinical samples were used in the validation. 6. There was no data correlating the results from the PerkinElmer PKamp Respiratory SARS-CoV-2 RT-PCR Panel 1 assay to the PerkinElmer New Coronavirus Nucleic Acid Detection Kit as stated

would be performed in the cover sheet. 7. During the survey on 04/27/2023 at 4:30 PM, the TP confirmed that no clinical samples were used in the validation to evaluate the RNase P IC and a correlation for SARS-CoV-2 results between the two testing kits was not documented as stated would be performed in the validation cover sheet.

D5429

MAINTENANCE AND FUNCTION CHECKS

CFR(s): 493.1254(a)(1)

For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer.

This STANDARD is not met as evidenced by:

Based on observation, review of instrument maintenance records, and interview with the testing person (TP), the laboratory failed to indicate which automated nucleic acid extraction instruments had routine preventive maintenance activities performed.

Findings: 1. The laboratory had nine Chemagic 360 automated nucleic acid extraction instruments that had been in use at different times in the past two years based on testing volume. 2. The monthly Chemagic 360 "Daily Maintenance Check List" log listed daily and weekly preventive maintenance activities to be performed on each instrument. 3. Laboratory records contained a single completed maintenance log for each month. The single log was used to document maintenance activities for whichever Chemagic 360 instruments were in use on those days/months. 4. The document did not indicate which of the nine Chemagic 360 instruments the daily and weekly maintenance activities were performed on. 5. During the survey on 04/27/2023 at 11:30 AM, the TP confirmed that the preventive maintenance log was being used to document performance of maintenance activities on whichever Chemagic 360 instruments were in use at the time and the log did not indicate which of the nine instruments maintenance was performed on.

D5775

COMPARISON OF TEST RESULTS

CFR(s): 493.1281(a)(c)

(a) If a laboratory performs the same test using different methodologies or instruments, or performs the same test at multiple testing sites, the laboratory must have a system that twice a year evaluates and defines the relationship between test results using the different methodologies, instruments, or testing sites. (c) The laboratory must document all test result comparison activities.

This STANDARD is not met as evidenced by:

Based on review of the procedure and test comparison records and interview with the testing person (TP), the laboratory failed to compare the virology polymerase chain reaction (PCR) test results between multiple instruments twice a year and failed to evaluate all assay targets. Findings: 1. The laboratory used the PerkinElmer New Coronavirus Nucleic Acid Detection Kit which identified three targets: the viral nucleocapsid (N) gene, the viral open reading frame 1ab gene (ORF1ab), and bacteriophage MS2 which was spiked into each sample as an internal control (IC). 2. The laboratory had five PCR instruments that had been in use at different times in 2022 and 2023 based on testing volume. 3. The laboratory's "Calibration Verification (AMR) & Assay Correlation Policy" stated that "If the laboratory has more than one platform or instrument that performs testing for a given analyte, they must perform an

assay correlation every 6 months to ensure that the results reported correlate with each other." 4. An instrument comparison between three PCR instruments was signed by the laboratory director on 01/17/2022 and 02/13/2023 (four instruments in total were compared between the two studies). The comparisons only evaluated results for the ORF1ab gene and did not address the N gene or the IC. 5. There was no documentation of a results comparison performed about halfway between the 01/17/2022 and 02/13/2023 comparisons. 6. During the survey on 04/27/2023 at 4:30 PM, the TP confirmed that only results from the ORF1ab gene were evaluated and a results comparison was not performed about six months after 01/17/2022.

D6091

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1445(e)(4)(iii)

The laboratory director must ensure all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action.

This STANDARD is not met as evidenced by:
Based on review of toxicology proficiency testing (PT) records and interview with the testing person (TP), the laboratory failed to implement a corrective action plan for unacceptable PT testing results. Findings: 1. Review of the toxicology PT records for the first event, 2022 Chemistry - Miscellaneous, showed that the laboratory failed to participate. 2. The documentation on the PT "Performance Review And Corrective Action" worksheet stated: "Samples analyzed against accepted criteria: passed." 3. The laboratory records did not include instrument printouts showing the results of the five PT specimens, a comparison of the results showing that they were acceptable, and corrective actions taken to ensure that the "failure to participate" would not recur. 4. During the survey on 04/27/2023 at 4:30 PM, the LD and TP confirmed that the documentation showing the analysis of the five specimens and comparison of the PT results to the target values were not available at the time of the survey.

D6149

GENERAL SUPERVISOR RESPONSIBILITIES
CFR(s): 493.1463(b)(1)

The director or technical supervisor may delegate to the general supervisor the responsibility for assuring that all remedial actions are taken whenever test systems deviate from the laboratory's established performance specifications.

This STANDARD is not met as evidenced by:
Based on review of the "Fridge Temperature Log" worksheets for the "samples" and "aliquots" and interview with the general supervisor (GS), the GS failed to ensure that the testing personnel were documenting the corrective actions when temperatures were outside of the acceptable ranges as required. Findings: 1. The "Fridge Temperature Log" worksheets for the "samples" refrigerator and "aliquots" refrigerator for the month of January 2023 were reviewed. The acceptable limit for each refrigerator is 2-8[degrees]Celsius (C). 2. During January 2023 the temperature value for the "sample" refrigerator was recorded as a value greater than 8C on 25 of 25 days that the laboratory was open. On the "Monthly Notes" section of the form the GS noted that there was an increase in temperatures from 1/16 - 1/22. 3. During January 2023 the temperature value for the "aliquots" refrigerator was recorded as a value less than 2C on 7 of 25 days that the laboratory was open. There were no

observations noted on the "Monthly Notes" section of the form. 4. The GS stated that the samples had been moved to a different refrigerator where the temperature was acceptable and then returned to the original refrigerator once the temperature was found to be acceptable. 5. During the survey on 04/27/2023 at 4:30 PM, the GS confirmed that there was no documentation on the worksheet stating that the temperature had been adjusted each day and found to be acceptable and that the samples had been moved to a different refrigerator where the temperature was acceptable and returned once the temperature was found to be acceptable.

D6175

TESTING PERSONNEL RESPONSIBILITIES
CFR(s): 493.1495(b)(1)

Each individual performing high complexity testing must follow the laboratory's procedures for specimen handling and processing, test analyses, reporting and maintaining records of patient test results.

This STANDARD is not met as evidenced by:
Based on review of the "Fridge Temperature Log" worksheets for the "samples" and "aliquots" and interview with the general supervisor (GS), the testing personnel failed to document corrective actions when temperatures were outside of the acceptable ranges as required. Cross refer to Tag D6149.