Department of Health & Human Services
Centers for Medicare & Medicaid Services

Form Approved
OMB No. 0938-0391

| Statement of Deficiencies | (X1) Provider/Supplier/CLIA Identification Number<br><br>09D0717493 | (X3) Date Survey Completed<br><br>03/11/2022 |
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| **Name of Provider or Supplier**<br><br>Bridgepoint Hospital National Harbor | **Street Address, City, State**<br><br>4601 Martin Luther King Ave Sw, Washington, DC | |
| 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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| **D3039** | RETENTION REQUIREMENTS<br>CFR(s): 493.1105(a)(5)<br><br>Quality system assessment records. Retain all laboratory quality system assessment records for at least 2 years.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of the written quality procedure, interview with the laboratory manager, and the lab supervisor, the laboratory failed to maintain meeting minutes that were documented during lab huddles. Findings: 1. The laboratory personnel started routine quality huddles in August 2020. 2. The meeting minutes were documented by the lab supervisor in August 2020. 3. During the interview with the lab supervisor he stated that the huddle meeting minutes were discarded. 4. The laboratory manager and lab supervisor confirmed that huddle meeting minutes were not maintained to ensure the quality of lab performance. |
| **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 review of the coagulation package insert, interview with the lab manager, and the testing person (TP), the laboratory failed to follow the package insert when performing the coagulation INR verification. Findings: 1. The laboratory performs coagulation testing on the Sysmex CS 2500. 2. The TP stated that he performs the |

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| | INR calculation when the reagent lot number changes. 3. The TP performed the INR manual calculation verification on 3/7/2022 with the incorrect ISI number. 4. The coagulation package insert states that the ISI number for the CS 2500 is 1.05. 5. The TP used 1.08 to perform the INR manual calculation verification on 3/7/2022. 6. The TP stated that he was not aware that the ISI number he used for INR verification was incorrect because the calculated values were within the normal ranges. 7. The TP confirmed that the ISI number used for the INR manual calculation verification was not the correct number stated in the manufacturer package insert. |
| **D5413** | TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT<br>CFR(s): 493.1252(b)<br><br>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.<br><br>This STANDARD is not met as evidenced by:<br>A. Based on review of temperature records and interview with the lead technologist, the laboratory failed to document accurate temperature values to ensure the laboratory's established criteria of acceptability. Findings: 1. The laboratory room temperature record for the month of January 2021 had temperature values and dates that were written over multiple times and was not legible. 2. Testing personnel did not document room temperatures each day patient testing was performed in January 2121. 3. The lead tech confirmed that the laboratory did not document accurate temperature values to ensure the laboratory's established criteria of acceptability. B. Based on review of temperature logs, interview the lab manager, and the testing person (TP), the laboratory failed to document room temperatures each day of patient testing when performing blood gases. Findings: 1. The laboratory performs blood gas testing on the Gem analyzer. 2. The lab manger stated that analyzer cartridges are stored in materials management once they are delivered at the loading dock. 3. The lab manager stated that cartridges are stored in the materials management area until needed for testing. 4. The manufacturers manual states that analyzer cartridges can be stored between 15-25C. 5. The lab was not documenting the storage area temperature each day of patient testing. 6. The lab manger and the TP confirmed that room temperatures were not documented each day of patient testing when performing blood gases. |
| **D5429** | MAINTENANCE AND FUNCTION CHECKS<br>CFR(s): 493.1254(a)(1)<br><br>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.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of maintenance records, interview with the lab manger, and the lead technologist, the laboratory failed to document accurate values for the chemistry analyzer. Findings: 1. The laboratory performs chemistry testing on the Dimensions |

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| | chemistry analyzer. 2. The laboratory performed system checks when performing maintenance procedures on the analyzer. 3. The documented values on the maintenance log for January 2121 had multiple write overs by lab staff and was not legible. 4. The lead tech confirmed that the laboratory did not document accurate system check values when performing chemistry maintenance procedures. |
| **D5783** | CORRECTIVE ACTIONS<br>CFR(s): 493.1282(b)(2)<br><br>(b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(2) Results of control or calibration materials, or both, fail to meet the laboratory's established criteria for acceptability. All patient test results obtained in the unacceptable test run and since the last acceptable test run must be evaluated to determine if patient test results have been adversely affected. The laboratory must take the corrective action necessary to ensure the reporting of accurate and reliable patient test results.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of chemistry quality control (QC) results, interview with the lab manager, and the lead tech, the laboratory failed to document all corrective action procedures when QC did not meet the laboratory's established criteria of acceptability. Findings: 1. The Vancomycin QC failed on 2/25/22. 2. The testing person (TP) repeated the QC twice. 3. The TP did not document the reason for the failure nor when a new bottle of QC was opened. 4. The TP did not document if patient results were affected to ensure accurate and reliable test results. 5. The lead tech confirmed that the TP did not document the reason for the QC failure, when new QC was opened, nor state if patient test results were affected. |
| **D5789** | TEST RECORDS<br>CFR(s): 493.1283(b)<br><br>Records of patient testing including, if applicable, instrument printouts, must be retained.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of the patient final report, interview with the lab manager, and the lead technologist the laboratory failed to maintain all patient test records. Findings: 1. The laboratory performed a CBC on Patient A on 12/24/20. The lab was unable to find the instrument printout. 2. The lab manger stated that the lab does not have the required space to store records for two years until the next survey. 3. The lab manager stated that some records were stored off site and that Patient A CBC instrument printout was stored off site and was not available for review. 4. The lab manager and the lead tech confirmed that all patient instrument result printouts were not available for review during the time of survey. |
| **D5805** | TEST REPORT<br>CFR(s): 493.1291(c)<br><br>The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where |

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| | the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of the patient final report and interview with the lab manager, the laboratory failed to have a system in place to identify when patient testing was performed at the laboratory's second location. Findings: 1. The laboratory had a chemistry test report for Patient B that was performed on 3/5/22. 2. The lab manger stated that testing was performed at their other location. 3. Review of the patient test report did not show a statement identifying that testing was performed at the second location. 4. The lab manager confirmed that Patient B chemistry test report did not show a statement identifying that testing was performed at the second location. |
| **D6087** | LABORATORY DIRECTOR RESPONSIBILITIES<br>CFR(s): 493.1445(e)(3)(iii)<br><br>The laboratory director must ensure that laboratory personnel are performing the test methods as required for accurate and reliable results.<br><br>This STANDARD is not met as evidenced by:<br>Based review of the written procedure, interview with the lab manger, and the testing person (TP), the laboratory director failed to ensure that the TP followed the written procedure when performing maintenance procedures on the urinalysis analyzer. Findings: Refer to D6177 |
| **D6094** | LABORATORY DIRECTOR RESPONSIBILITIES<br>CFR(s): 493.1445(e)(5)<br><br>The laboratory director must ensure that the quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of the written quality procedure and interview with the lab manager, the laboratory director (LD) failed to ensure that quality assessments (QA) procedures were performed and maintained. Findings: Refer to D3039 and D6177 1. The lab manager and the lab director started QA meetings in September 2020. 2. The lab manger and the lab director started meeting to discuss the new testing added in the laboratory. 3 During the September 2020 QA meeting the lab manager and the lab director discussed establishing a dashboard with select indicator for physicians and administrators. 4. During the Q4 meeting in 2020 with the lab director. The lab was not meeting CBC target threshold values. Values were highlighted in red and trending on the dashboard. 5. The LD failed to discuss with lab staff during the October and November 2020 QA lab huddle that CBC target threshold values were trending and not being meet. 6. The lab staff did not document meeting minutes during the October and November 2020 QA lab huddle nor discuss remedial action procedures for CBC target threshold values that were trending and not being meet. 7. The laboratory |

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| | personnel started routine quality lab huddles in August 2020. 8. The huddle meeting minutes were supposed to be documented and maintained by the lab supervisor. 9. The LD failed to ensure that lab staff documented and maintained huddle meeting minutes from August 2020 to October 2021. 10. The laboratory performs hematology slide stains for peripheral blood smears. 11. The LD failed to ensure that lab staff documented stain QA checks each day of patient testing. 12. The lab manager confirmed that the LD failed to ensure that all QA procedures were performed and maintained to ensure accurate and reliable patient testing. |
| **D6096** | LABORATORY DIRECTOR RESPONSIBILITIES<br>CFR(s): 493.1445(e)(7)<br><br>The laboratory director must ensure that all necessary remedial actions are taken and documented whenever significant deviations from the laboratory's established performance characteristics are identified.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of chemistry quality control (QC) results, interview with the lab manager, and the lead tech, the laboratory director failed to ensure that lab staff documented all corrective action procedures when QC did not meet the laboratory's established criteria of acceptability. Findings: Refer to D5783 |
| **D6098** | LABORATORY DIRECTOR RESPONSIBILITIES<br>CFR(s): 493.1445(e)(8)<br><br>The laboratory director must ensure that reports of test results include pertinent information required for interpretation.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of the patient final report and interview with the lab manager, the laboratory director failed to have a system in place to identify when patient testing was performed at the laboratory's second location. Findings:Refer to D5805 |
| **D6127** | TECHNICAL SUPERVISOR RESPONSIBILITIES<br>CFR(s): 493.1451(b)(9)<br><br>The technical supervisor is responsible for evaluating and documenting the performance of individuals responsible for high complexity testing at least semiannually during the first year the individual tests patient specimens.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of competency records and interview with the lab manager acting as the technical supervisor (TS), the TS failed to ensure that competency procedures were performed for all areas of the laboratory including all laboratory personnel Findings: 1. Testing person B hired May 2021 did not have semiannual competency procedures performed during the year 2021. 2. Testing person A hired on 11/11/2019 had semiannual competency procedures performed on 12/5/20. 3. The TS confirmed that competency procedures were not performed for all areas of the laboratory including all laboratory personnel. |
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| **D6128** | TECHNICAL SUPERVISOR RESPONSIBILITIES<br>CFR(s): 493.1451(b)(9)<br><br>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.<br><br>This STANDARD is not met as evidenced by:<br>A. Based on review of competency records and interview with the lab manager acting as the technical supervisor (TS), the TS failed to ensure that competency procedures were performed for all areas of the laboratory including all laboratory personnel Findings: 1. The laboratory performs Microbiology Gram Staining, Hematology cell morphology, and urine sedimentation morphology. 2. The TS did not perform annual competency checks nor direct observations procedures for testing personnel during the year 2021. 3. Testing person A hired on 11/11/2019 did not have annual competency performed during the year 2020. Annual competency procedures were performed from 1/1/2021-12-31/2021. 4. The TS confirmed that that competency procedures were not performed for all areas of the laboratory including all laboratory personnel.<br>B. Based on review of competency records and interview with the lab manager acting as the technical supervisor (TS). The TS failed to ensure that competency procedures were reviewed and signed by all required laboratory personnel. Findings: 1.Testing personnel (TP) performed quality control procedures for annual competency on the chemistry analyzer. 2. Results were documented on the laboratory log sheet with the date and initials of the TP performing testing. 3. The log sheet had at the top of the page spaces for the instrument name, date, and year which was not documented by the TS. 4. The log sheet was not reviewed and signed by the TS in the verified and date space at the bottom of the log sheet. 5. The TS confirmed that competency procedures were not reviewed and signed by all required laboratory personnel. |
| **D6177** | TESTING PERSONNEL RESPONSIBILITIES<br>CFR(s): 493.1495(b)(3)<br><br>Each individual performing high complexity testing must adhere to the laboratory's quality control policies, document all quality control activities, instrument and procedural calibrations and maintenance performed.<br><br>This STANDARD is not met as evidenced by:<br>A. Based review of the written procedure, interview with the lab manger, and the testing person (TP), the TP failed to follow the written procedure when performing maintenance procedures on the urinalysis analyzer. Findings: 1. The laboratory performs urinalysis testing on the Clinitek analyzer. 2. The laboratory had plastic eating utensils in one of the laboratory drawers. 3. The TP stated that she uses the plastic spoon to perform maintenance procedures on the analyzer. 4. The TP stated that she transfers hot water to the sensor on the analyzer when performing maintenance procedures. She stated that this is what she was taught in training by the analyzer manufacturer. 5. The TP did not explain the use for the plastic fork and knife that was also in the laboratory drawer. 6. The Clinitek written procedure states to use a plastic dropper to dispense hot water into the analyzer well. 7. The lab manager confirmed that the TP failed to follow the written procedure when performing |

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| | maintenance procedures on the urinalysis analyzer. B. Based review of the hematology staining procedure and interview with the lab manger, the testing personnel failed to document the stain quality each day of patient testing. Findings: 1. The laboratory performs hematology slide stains for peripheral blood smear review, 2. The laboratory failed to perform stain quality checks each day of patient testing. 3. The written procedure states to monitor the stain quality of the smear to ensure that the stain is free of precipitate and has good cell distribution. 4. The lab manager confirmed that testing personnel failed to document the stain quality each day of patient testing. |