| **Statement of Deficiencies** | **(X1) Provider/Supplier/CLIA Identification Number** | **(X3) Date Survey Completed** |
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| | 21D2011505 | 10/17/2022 |
| **Name of Provider or Supplier** | **Street Address, City, State** | |
| Cigna Healthspring Livingwell Center | 312 N Martin Luther King Jr Blvd Suite 200, Baltimore, 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 |
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| **D2009** | TESTING OF PROFICIENCY TESTING SAMPLES<br>CFR(s): 493.801(b)(1)<br><br>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.<br><br>This STANDARD is not met as evidenced by:<br>Based on proficiency testing (PT) record review and interview with testing personnel (TP), the laboratory failed to ensure that the laboratory director (LD) signed PT attestation statements, attesting that PT specimens were run in the same way as patient samples. Findings: 1. A review of hematology and chemistry PT records from 2022 showed that the LD did not sign the attestation statements for 2 out of 2 events in hematology and 2 out of 3 events in chemistry. 2. During an interview on 10/17/2022 at 2:00 PM, TP #1 confirmed that the attestation statements were not signed by the LD. |
| **D3009** | FACILITIES<br>CFR(s): 493.1101(c)<br><br>The laboratory must be in compliance with applicable Federal, State, and local laboratory requirements.<br><br>This STANDARD is not met as evidenced by:<br>Based on quality control (QC) record review and interview with testing personnel (TP), the laboratory did not ensure that State and Federal requirements were followed when performing QC on the i-STAT handheld blood analyzer. Findings: 1. The laboratory performs chemistry and hematology testing on 2 i-STAT blood analyzers, |

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| | labeled as "India" (serial #330942) and "Hotel" (serial #330621) 5 days a week. The laboratory performs testing using cartridges for brain natriuretic peptide (BNP), cardiac troponin I (cTnI), CHEM8+ (Sodium, Potassium, Chloride, TCO2, Ionized Calcium, Glucose, Urea Nitrogen/Urea Creatinine, and Hematocrit), and PT/INR (prothrombin time/international normalized ratio). 2. A review of QC records for the i-STAT analyzer between January and October 2022 showed that QC for these tests was run weekly from 01/07/2022 through 05/13/2022. There was a 2 week gap between running QC from 06/03/2022 to 06/17/2022; 06/30/2022 to 07/08/2022; and 08/19/2022 to 09/02/2022. There was a 3 week gap between running QC from 09/02 /2022 to 09/21/2022 and 09/21/2022 to 10/10/2022. 3. Code of Maryland Regulations-COMAR 10.10.06 Medical Laboratories-Quality Assurance, .06 Quality Control - Single-Use Test Devices, B. Standards, (6) Quality Control Tests, (a) Quantitative Test Systems states, "A licensee shall ensure that quality control testing for a quantitative test system is performed and documented using at least two levels of control material before patient testing" "At least weekly for each lot of a single-use test device used for patient testing." 4. During an interview on 10/17/2022 at 2:00 PM, TP #1 confirmed that the laboratory was not in compliance with the State requirements to run QC at least weekly when performing patient testing. |
| **D3031** | RETENTION REQUIREMENTS<br>CFR(s): 493.1105(a)(3)<br><br>Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years.<br><br>This STANDARD is not met as evidenced by:<br>Based on laboratory record review and interview with testing personnel (TP), the laboratory failed to retain all analytic systems records for at least 2 years. Findings: 1. A review of quality control (QC) records from 12/3/2021 through 10/10/2022 for the i-STAT handheld blood analyzer showed that there were no instrument printouts for QC present at the time of the survey. 2. A review of calibration records from 2020 to 2022 showed that there were no instrument printouts for calibrations run on the i-STAT present at the time of the survey. 3. During an interview on 10/17/2022 at 9:40 AM, TP #1 stated that they copy the QC and calibration information on to a separate form and do not print out and save the results. |
| **D3037** | RETENTION REQUIREMENTS<br>CFR(s): 493.1105(a)(4)<br><br>Proficiency testing records. Retain all proficiency testing records for at least 2 years.<br><br>This STANDARD is not met as evidenced by:<br>Based on proficiency testing (PT) record review and interview with testing personnel (TP), the laboratory did not ensure that a copy of all PT documents was maintained by the laboratory for a minimum of two years from the date of the PT testing event. Findings: 1. A review of PT records from 2022 showed that PT results and scores from the PT provider were not available at the time of the survey for 2 out of 2 events in hematology and 3 out of 3 events in chemistry. 2. During an interview on 10/17 /2022 at 11:40 AM, TP #1 confirmed that the laboratory did not maintain all PT documents for a minimum of two years from the date of the PT testing event. |

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| **D5439** | CALIBRATION AND CALIBRATION VERIFICATION<br>CFR(s): 493.1255(b)<br><br>Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3) -- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification.<br><br>This STANDARD is not met as evidenced by:<br>Based on calibration record review and interview with testing personnel (TP), the laboratory failed to perform and document calibration verification procedures for the i-STAT handheld blood analyzer at least once every 6 months. Findings: 1. The laboratory performs chemistry and hematology testing on 2 i-STAT blood analyzers, labeled as "India" (serial #330942) and "Hotel" (serial #330621). The laboratory performs testing using cartridges for brain natriuretic peptide (BNP), cardiac troponin I (cTnI), CHEM8+ (Sodium, Potassium, Chloride, TCO2, Ionized Calcium, Glucose, Urea Nitrogen/Urea Creatinine, and Hematocrit), and PT/INR (prothrombin time /international normalized ratio). 2. A review of calibration records from 2020 to 2022 showed that testing personnel hand-wrote the calibration results for BNP, cTnI, and CHEM8+ on a "Calibration Verification" sheet. No calibration reference sheets or instrument printouts were available at the time of the survey and there was no way to confirm that the calibration verification was successful. 3. "Calibration Verification" sheets were reviewed for 2/2020 (cTnI, BNP); 9/2020 (cTnI, BNP, CHEM8+); 5/2021 (cTnI, BNP, CHEM8+); 11/2021 (BNP, CHEM8+); 6/2022 (cTnI, CHEM8+); and 7 /2022 (BNP). There was 1 "Calibration Verification" sheet for each cartridge for each date of testing for the 2 analyzers. During an interview at 11:20 AM on the day of the survey, TP #1 stated that they would run the BNP calibration on 1 i-STAT and cTnI on the second i-STAT because the test "takes so long." 4. The "Calibration Verification" sheets were not labeled with the name of the i-STAT analyzer which was calibrated. There was no way to identify which test cartridge had been calibrated on which analyzer. TP #1 confirmed that each test had not been calibrated on each i-STAT analyzer although both i-STAT analyzers are used to perform all the tests available. 5. Record review showed that there were no "Calibration Verification" sheets for PT/INR. TP #1 stated at 11:20 AM that calibrations were not performed on the i-STAT for the test PT/INR. 6. During an interview on 10/17/2022 at 2:00 PM, TP |

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| | #1 confirmed that the laboratory failed to perform and document calibration verification procedures for each i-STAT handheld blood analyzer least once every 6 months. |
| **D5445** | CONTROL PROCEDURES<br>CFR(s): 493.1256(d)(1)(2)(g)<br><br>Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- (d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493.1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (g) The laboratory must document all control procedures performed.<br><br>This STANDARD is not met as evidenced by:<br>Based on quality control (QC) record review and interview with testing personnel (TP), the laboratory did not run 2 levels of QC each day of patient testing and failed to establish an Individualized Quality Control Plan (IQCP) for performing testing on the i-STAT handheld blood analyzer. Findings: 1. The laboratory performs chemistry and hematology testing on 2 i-STAT blood analyzers, labeled as "India" (serial #330942) and "Hotel" (serial #330621) 5 days a week. QC record review from January through October 2022 showed that the laboratory failed to run 2 levels of QC each day of patient testing. Refer to D3009 for details. 2. During an interview on 10/17/2022 at 9: 40 AM, TP #1 stated that the laboratory did not have an IQCP in place to reduce the amount of QC required when performing testing on the i-STAT and confirmed that the laboratory failed to run 2 levels of QC each day of patient testing on each analyzer. |
| **D5775** | COMPARISON OF TEST RESULTS<br>CFR(s): 493.1281(a)(c)<br><br>(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.<br><br>This STANDARD is not met as evidenced by:<br>Based on procedure manual and record review and interview with testing personnel (TP), the laboratory failed to evaluate and define the relationship between test results using different instruments twice a year, and to document all test result comparison activities. Findings: 1. The laboratory performs chemistry and hematology testing on 2 i-STAT blood analyzers, labeled as "India" (serial #330942) and "Hotel" (serial #330621). See D3009 for details. 2. Procedure manual review showed that the laboratory had no written policy for performing and evaluating the correlations between the two analyzers twice a year; and 3. The procedure should include, but is not limited to: the details of whom the samples will be exchanged with, how often split samples will be tested, what the acceptable limits of the comparison are, and remedial actions to be taken when the results are not within acceptable limits. 4. |

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| | Record review showed that there was no documentation that test result comparisons had been performed between the 2 analyzers. This was confirmed by TP #1 during an interview on 10/17/2022 at 10:10 AM. |
| **D6018** | LABORATORY DIRECTOR RESPONSIBILITIES<br>CFR(s): 493.1407(e)(4)(iii)<br><br>The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(4)(iii) Ensure that 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;<br><br>This STANDARD is not met as evidenced by:<br>Based on proficiency testing (PT) record review and interview with testing personnel (TP), the laboratory director (LD) did not ensure that all PT reports were reviewed to evaluate the laboratory's performance and to identify any problems that require corrective action. Findings: 1. A review of hematology and chemistry PT records from 2022 showed that the PT results summaries were not present at the time of the survey for 2 out of 2 events in hematology and 3 out of 3 events in chemistry. 2. During an interview at 11:40 AM on the day of the survey, TP #1 stated that the LD reviews the results online and lets the laboratory staff know if there is a problem. There was no documentation available at the time of the survey showing that the LD had reviewed the PT results. 3. During an interview on 10/17/2022 at 2:00 PM, TP #1 confirmed that PT results were not reviewed and signed by the LD. |
| **D6022** | LABORATORY DIRECTOR RESPONSIBILITIES<br>CFR(s): 493.1407(e)(5)<br><br>The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(5) Ensure that the quality control and quality assessment programs are established and maintained to identify failures in quality as they occur.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of the quality assurance (QA) plan, procedure manual and document review, and interview with testing personnel (TP), the laboratory director (LD) failed to ensure that quality control (QC) and QA procedures monitored overall operation of the laboratory to identify immediate QC failures and ensure that effective corrective actions are taken when failures are identified. Findings: 1. Procedure manual review showed a blank form, "Cigna Healthspring Living Well Center - Quality Assurance Chart Audit Review Tool." The form states that "A total of five (5) charts will be pulled from various specialties during the scheduled HealthCare Center Review." "The test order, test result and initial of person performing test should be written in the chart for CLIA compliance. Record C=Compliant, NC=Non-compliant (complete comment section if NC) under each test evaluated." 2. During an interview at 1:00 PM on the day of the survey TP #1 stated that the laboratory was not performing the chart |

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| | audit. 3. The "Bravo Health Advanced Care Center - Laboratory Refrigerator - Daily - Temperature Record Log" states that "Designated Supervisor or CLIA Contact to review and initial each month in first shaded area above. Practice Administrator should initial second shaded area." A review of refrigerator temperature logs from January through September, 2022 showed that there were no initials showing that refrigerator temperatures had been reviewed monthly for 9 out of 9 months. 4. The laboratory failed to ensure that the LD signed proficiency testing (PT) attestation statements, attesting that PT specimens were run in the same way as patient samples. Cross-refer to D2009. 5. The laboratory did not ensure that State and Federal requirements were followed when performing QC on the i-STAT handheld blood analyzer. Cross-refer to D3009. 6. The laboratory failed to retain all analytic systems records for at least 2 years. Cross-refer to D3031. 7. The laboratory did not ensure that a copy of all PT documents was maintained by the laboratory for a minimum of two years from the date of the PT testing event. Cross-refer to D3037. 8. The laboratory failed to perform and document calibration verification procedures for the i-STAT handheld blood analyzer least once every 6 months. Cross-refer to D5439. 9. The laboratory did not run 2 levels of QC each day of patient testing and failed to establish an Individualized Quality Control Plan for performing testing on the i-STAT handheld blood analyzers. Cross-refer to D5445. 10. The laboratory failed to evaluate and define the relationship between test results using different instruments twice a year, and to document all test result comparison activities. Cross-refer to D5775. 11. The LD did not ensure that all PT reports were reviewed to evaluate the laboratory's performance and to identify any problems that require corrective action. Cross-refer to D6018. 12. During an interview on 10/17/2022 at 2:00 PM, TP #1 confirmed that the LD failed to ensure that the QC and QA programs were established and maintained to identify failures in quality as they occur. |
| **D6030** | LABORATORY DIRECTOR RESPONSIBILITIES<br>CFR(s): 493.1407(e)(12)<br><br>The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(12) Ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills;<br><br>This STANDARD is not met as evidenced by:<br>Based on procedure manual and competency assessment record review and interview with testing personnel (TP), the laboratory director (LD) did not ensure that policies and procedures were established and followed to monitor the competency of all personnel who conduct preanalytic, analytic, and postanalytic phases of testing. Findings: 1. The laboratory currently has 2 TP listed on the "Laboratory Personnel Report (CLIA)" (CMS-209). One of 2 TP have been testing for less than 6 months. 2. A review of competency assessment records from 2020 to 2022 showed that there were no competency assessments for the i-STAT handheld blood analyzer for 1 of 1 TP. A quiz was found that had been taken by TP #1 on 03/10/2022, however the quiz had not been scored or signed by the LD. 3. Procedure manual review showed that the |

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| | procedure, "Quality Assurance" "Monitoring of Indicators," "E. Personnel Assessment (493.1713)" states, "The laboratory will document (new) employee initial training and competency for tasks they perform. API Proficiency Program will be used to insure on-going personnel competency for waived complexity testing. Authorizations to perform tests and competency evaluations will be reviewed, signed/dated by the Clinical Supervisor." 4. The laboratory performs moderate complexity hematology and chemistry testing in addition to waived testing. The procedure does not say how to perform competency assessments on the TP or who the Clinical Supervisor is. A review of the CMS-209 and TP credentials showed that the LD qualifies as the technical consultant and is responsible for monitoring and evaluating the competency of the TP. 5. During an interview on 10/17/2022 at 2:00 PM TP #1 confirmed that the LD failed to ensure that the laboratory established and followed procedures for monitoring the competency of the TP. |
| **D6031** | LABORATORY DIRECTOR RESPONSIBILITIES<br>CFR(s): 493.1407(e)(13)<br><br>The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(13) Ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process;<br><br>This STANDARD is not met as evidenced by:<br>Based on standard operating procedure manual (SOPM) review and interview with testing personnel (TP), the laboratory director (LD) failed to ensure that the laboratory's SOPM was current and approved by the LD. Findings: 1. The procedure, "Quality Assurance Program" "Scope of Care" states "A. The laboratory performs only waived complexity testing." The laboratory performs moderate complexity hematology and chemistry testing in addition to waived testing. 2. The SOPM does not include an up-to-date procedure for performing competency assessments on the TP. Cross-refer to D6030. 3. The "i-STAT Procedure Manual" was not approved (signed and dated) by the LD; and 4. The procedure, "Procedure Manual for the i-STAT System" has the note "REV. DATE: 23 Nov 2009" printed at the bottom of the pages. The procedures in this SOPM are out of date. The procedure states that controls for brain natriuretic peptide and cardiac troponin I should be stored at less than or equal to "-18F (-1C) in a non-defrosting freezer." Instructions printed on the outside of the box for these controls shows that they can be stored at 2-8C in the refrigerator. 5. During an interview on 10/17/2022 at 10:30 AM TP #1 confirmed that the LD failed to ensure that a current, approved procedure manual is available to all personnel responsible for any aspect of the testing process. |
| **D6046** | TECHNICAL CONSULTANT RESPONSIBILITIES<br>CFR(s): 493.1413(b)(8)<br><br>(b) The technical consultant is responsible for-- (b)(8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently.<br><br>This STANDARD is not met as evidenced by: |

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| | The laboratory director acting as the technical consultant failed to perform and document the competency reviews on all TP, assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately, and proficiently. Cross-refer to D6030. |