Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D0994320	06/30/2023
Name of Provider or Supplier	**Street Address, City, State**	
Burzynski Clinic	9432 Old Katy Road, Suite 200, Houston, TX	

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
D0000	Noted deficiencies and plans of correction were discussed with the laboratory representative(s) at the exit conference. The facility was found to be in compliance with applicable Conditions in the CLIA program, and recertification is recommended.
D2015	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(5)(6) (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. This STANDARD is not met as evidenced by: Based on review of laboratory's proficiency testing (PT) records for 2021, 2022 and 2023, laboratory's policies/procedures and staff interview, the laboratory failed to retain all PT documents for 1 of 10 PT events reviewed as per laboratory's protocols. Findings included: 1. Review of laboratory's PT records for 2021, 2022 and 2023 revealed the following 1 of 10 reviewed PT events did not have documentation of signed attestation statement or review of PT performance evaluation: American Proficiency Institute 2022 Chemistry - Core - 2nd Event 2. Review of laboratory's "Proficiency Testing Policy" (last revised 12/07/2021) revealed: "The proficiency report is to be signed by testing personnel, secondary reviewer and the Lab Director. This form is to be placed with instrument printouts, or copies of worksheets, and maintained in the laboratory for at least two years." 3. In an interview on 06/29/2023

	at 1405 hours in the patient treatment room number three, the laboratory's Technical Consultant (as indicated on submitted form CMS 209) confirmed the above documents could not be located for review. Key: CMS - Centers for Medicare and Medicaid
D5221	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(d) All proficiency testing evaluation and verification activities must be documented. This STANDARD is not met as evidenced by: Based on review of laboratory's proficiency testing (PT) records for 2021, 2022 and 2023, laboratory's policies/procedures and staff interview, the laboratory failed to document corrective action for 1 of 1 unacceptable performance for Chloride as per laboratory's protocols. Findings included: 1. Review of laboratory's PT records for 2021, 2022 and 2023 revealed the following 1 of 1 unacceptable PT performance for Chloride: American Proficiency Institute 2023 Chemistry - Core - 1st Event Analyte: Chloride Sample: CH-1 Result: 100 Expected Result: 89-99 Performance: Unacceptable 2. Further review of the records for the American Proficiency Institute 2023 Chemistry - Core - 1st Event revealed there was no documentation of corrective action for the unacceptable result. 3. Review of laboratory's "Proficiency Testing Policy" (last revised 12/07/2021) revealed: "Document findings and corrective actions; keep all paperwork together with report." 4. In an interview on 06/29/2023 at 1405 hours in the patient treatment room number three, the laboratory's Technical Consultant (as indicated on submitted form CMS 209), after review of the data, confirmed the findings. Key: CMS - Centers for Medicare and Medicaid
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 the direct observation of the surveyor, review of manufacturer's packages, the laboratory's temperature logs from January 2023 to June 2023, patient results, and confirmed in an interview, the laboratory failed to store QC materials according to manufacturer's instructions for two of two QC materials for 19 of 50 days reviewed on i-STAT analyzer. The findings were: 1. The surveyor's direct observation on 6/29 /2023 at 9:30 am in the treatment room #2 refrigerator revealed the refrigerator stored two of two i-STAT controls, i-STAT TriControl 1 Lot#: 301157 Exp. 2024-01-31 i-STAT TriControl 3 Lot#: 321157 Exp. 2024-01-31 2. Further review of i-STAT Tricontrol packages revealed the temperature requirement was from 2-8C. 3. The surveyor's direct observation on 6/29/2023 at 9:40 am in the treatment room #2, the temperature reading for refrigerator revealed to be 9.1C. 4. Random review of the laboratory's temperature logs from January 2023 to June 2023 revealed 19 of 50 days

	reviewed were out of the manufacturer's instruction temperature ranges. 2/23/2023 1.1 C 2/24/2023 1.5C 2/25/2023 0.5C 2/26/2023 1.5C 3/25/2023 8.1C 3/30/2023 8.1C 5/6 /2023 8.2C 5/18/2023 12.7C 5/19/2023 8.2C 5/20/2023 8.2C 5/25/2023 9.1C 5/26 /2023 8.2C 5/27/2023 8.9C 5/30/2023 8.8C 6/12/2023 9.2C 6/13/2023 8.5C 6/14/2023 9.1C 6/27/2023 9.0C 6/29/2023 9.0C 5. Random review of the laboratory's patient results for the above dates revealed 16 patients had testing on i-STAT analyzer. 2/23 /2023 MR#: 26849 2/23/2023 MR#: 26867 2/24/2023 MR#: 26837 3/30/2023 MR#: 26948 5/6/2023 MR#: 26993 5/18/2023 MR#: 26874 5/18/2023 MR#: 27056 5/19 /2023 MR#: 27042 5/19/2023 MR#: 27055 5/20/2023 MR#: 27065 6/12/2023 MR#: 26968 6/13/2023 MR#: 27060 6/14/2023 MR#: 26924 6/27/2023 MR#: 26847 6/29 /2023 MR#: 26968 6/29/2023 MR#: 27043 6. An interview with the technical consultant on 6/29/2023 at 2:40 pm in the treatment room #3 confirmed the above findings.
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 review of manufacturer instructions for use for the Vital Diagnostics Envoy 500 chemistry analyzer, review of laboratory's maintenance records for its Envoy 500 instrument for September 2022 to May 2023 and staff interview, the laboratory failed to keep up and/or document instrument maintenance for 10 of 10 instances it was required. Findings included: 1. Review of manufacturer instructions for use for the Vital Diagnostics Envoy 500 chemistry analyzer (document L7109, Rev. E) revealed the following maintenance was required on the instrument: "Daily 7.2.1 Check and Replenish Rinse Solution ... 7.2.2 Empty Waste Container ... 7.2.3 Archive "Specimen Log" ... 7.2.4 Backup Patient Archive ... 7.2.5 Clear Alert Message Logs ... 7.2.6 Suspend Activity ... Weekly 7.2.7 Wipe the sample needles ... 7.2.8 Perform a Shutdown ... 7.2.9 Extra Wash Cuvettes ... Monthly 7.2.10 Replace ISE Ground By-Pass Tube ... 7.2.11 Perform Quality Control Backup ... Quarterly 7.2.12 K, Chloride, and CO2 Electrode Replacement ... 7.2.13 Replace all components of the Envoy Maintenance Kit ... Semi-Annual (6 Month) 7.2.14 Replace Peristaltic Pump Cartridge ... Annual 7.2.15 Sodium and Reference Electrode Replacement ... 7.2.16 Fluidics tubing replacement ..." 2. Review of laboratory's maintenance records for its Envoy 500 instrument (serial number 43110883, placed in use 03/27/2012) for September 2022 to May 2023 revealed the performance of the following maintenance components was not documented, or was documented beyond the required maintenance frequency: a. Daily Maintenance not documented for: 03/20/2023 03/21 /2023 03/22/2023 03/23/2023 03/27/2023 03/28/2023 03/29/2023 03/30/2023 b. Quarterly maintenance for replacement of K Electrode exceeded 3 months: Last replacement documented: 01/19/2023 Next replacement documented: 05/23/2023 Time elapsed: 5 months c. Semi-annual maintenance exceeded 6 months: Last documented: 09/07/2022 No further documentation of semi-annual maintenance after September 2022. Time elapsed: 9 months 3. In an interview on 06/29/2023 at 1110 hours in the patient treatment room number three, the laboratory's Technical Consultant (as indicated on submitted form CMS 209), after review of the data, confirmed the findings. Key: CMS - Centers for Medicare and Medicaid

D5437	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(a) Unless otherwise specified in this subpart, for each applicable test system the laboratory must perform and document calibration procedures-- (1) Following the manufacturer's test system instructions, using calibration materials provided or specified, and with at least the frequency recommended by the manufacturer; (2) Using the criteria verified or established by the laboratory as specified in 493.1253(b)(3)-- (2)(i) Using calibration materials appropriate for the test system and, if possible, traceable to a reference method or reference material of known value; and (2)(ii) Including the number, type, and concentration of calibration materials, as well as acceptable limits for and the frequency of calibration; and (3) Whenever calibration verification fails to meet the laboratory's acceptable limits for calibration verification. This STANDARD is not met as evidenced by: Based on the review of the laboratory's policy, calibration verification records in 2022, CMS 116 application, and confirmed in an interview, the laboratory failed to have documentation for one of two calibration verification records in 2022 on one of one i-STAT analyzer performing CHEM8+ Cartridge. The findings were: 1. Review of the laboratory's policy titled Calibration, Calibration Verification, effective date: Dec 15, 2020, protocol for I-Stat revealed "All laboratory instruments will be calibrated and verified using material specified by the manufacturer according to the recommendation when any of the following conditions occur:... 3. At least every six months..." 2. Review of the laboratory's calibration verification records in 2022 revealed the laboratory failed to have documentation for one of two calibration verification records in 2022 on i-STAT analyzer (SN:416390). 3. Review of the laboratory's CMS 116 application, signed by the LD on 6/15/2023, revealed the annual routine chemistry volume was 3000. 4. An interview with the technical consultant on 6/29/2023 at 11:15 am in the treatment room #3 confirmed the above findings. Key: CMS=Center for Medicare and Medicaid Services
D5441	CONTROL PROCEDURES CFR(s): 493.1256(a)(b)(c)(g) (a) For each test system, the laboratory is responsible for having control procedures that monitor the accuracy and precision of the complete analytic process. (b) The laboratory must establish the number, type, and frequency of testing control materials using, if applicable, the performance specifications verified or established by the laboratory as specified in 493.1253(b)(3). (c) The control procedures must-- (c)(1) Detect immediate errors that occur due to test system failure, adverse environmental conditions, and operator performance. (c)(2) Monitor over time the accuracy and precision of test performance that may be influenced by changes in test system performance and environmental conditions, and variance in operator performance. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on the review of the laboratory's quality control records in 2022, CMS 116 application, and confirmed in an interview, the laboratory failed to have documentation of monitoring quality control values over time for CHEM8+ cartridge on i-STAT analyzer for 12 of 12 months reviewed. The findings were: 1. Review of the laboratory's quality control records in 2022 revealed no documentation of

	monitoring quality control values over time for CHEM8+ cartridge on i-STAT analyzer for 12 of 12 months reviewed. 2. Review of the laboratory's CMS 116 application, signed by the LD on 6/15/2023, revealed the annual routine chemistry volume was 3000. 3. An interview with the technical consultant on 6/29/2023 at 2:39 pm in the treatment room #3 confirmed the above findings. Key: CMS=Center of Medicare and Medicaid Services
D6053	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least semiannually during the first year the individual tests patient specimens. This STANDARD is not met as evidenced by: Based on the review of the CMS 209 Laboratory Personnel Report, the laboratory's personnel competency records, and confirmed in an interview, the Technical Consultant (TC) failed to document competency assessments at least semiannually during the first year for one of five testing personnel (TP) for i-STAT analyzer. The findings were: 1. Review of the CMS Report 209 Laboratory Personnel Report revealed the laboratory listed five testing personnel performing moderate complexity testing of i-STAT analyzer (SN: 416390). 2. Review of the laboratory's personnel competency records revealed no documentation for one of two competency assessments during the first year for one of five testing personnel. TP#3 hired date: 6/1 /2022 3. An interview with the technical consultant on 6/29/2023 at 10:22 am in the treatment room #3 confirmed the above findings.