

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D0994320	(X3) Date Survey Completed 07/14/2025
Name of Provider or Supplier Burzynski Clinic	Street Address, City, State 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	A recertified onsite survey was completed on 07/14/2025. 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.
D5413	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b)</p> <p>(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: (b)(1) Water quality. (b)(2) Temperature. (b)(3) Humidity. (b)(4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.</p> <p>This STANDARD is not met as evidenced by: Based on the direct observation of the surveyor, review of manufacturer's packages and package insert, the laboratory's temperature log, random review of the laboratory's temperature logs from June 2024 to August 2024 and May 2025 to June 2025, patient results, and confirmed in an interview, the laboratory failed to store 3 of 3 i-STAT materials according to manufacturer's instructions for 25 of 153 days reviewed on i-STAT analyzer (SN: 416390). The findings were: 1. The surveyor's direct observation on 7/17/2025 at 12:15 pm in the IV room, the refrigerator revealed storing i-STAT CHEM8+ cartridges and 2 levels of i-STAT Tricontrols. i-STAT CHEM8+ Cartridges Lot#: H25048 Exp.2025-08-16 i-STAT TriControl 1 Lot#: 301179 Exp. 2025-11-30 i-STAT TriControl 3 Lot#: 321179 Exp. 2025-11-30 2. Further review of i-STAT Tricontrol packages revealed the temperature requirement was from 2-8C (35-46F). 3. Review the manufacturer's package insert titled i-STAT CHEM8+ Cartridges (Rev.</p>

Date: 06-Nov-2020 Art: 765859-01 Rev. B) under Storage Conditions revealed "Refrigeration at 2-8C (35-46F) until expiration date." 4. Random review of the laboratory's temperature logs from June 2024 to August 2024 and May 2025 to June 2025 revealed 25 of 153 days reviewed were out of the temperature ranges according to the manufacturer's instructions. 06/12/2024 8.4C 06/13/2024 8.6C 06/18/2024 8.6C 06/19/2024 8.2C 06/20/2024 8.2C 06/24/2024 8.9C 06/26/2024 8.6C 07/03/2024 8.9C 07/17/2024 8.9C 08/01/2024 8.1C 08/12/2024 8.5C 05/29/2025 9.9C 05/30/2025 10.1C 05/31/2025 9.9C 06/02/2025 10.2C 06/04/2025 8.2C 06/05/2025 8.2C 06/06/2025 8.3C 06/07/2025 8.2C 06/09/2025 8.2C 06/10/2025 8.1C 06/11/2025 8.1C 06/14/2025 8.1C 06/17/2025 8.2C 06/24/2025 8.1C 5. Review of the laboratory's patient results for the above dates revealed the laboratory performed 10 tests on i-STAT analyzer. 06/12/2024 MRN#: 27391 06/12/2024 MRN#: 27397 06/18/2024 MRN#: 27391 06/18/2024 MRN#: 26886 06/18/2024 MRN#: 27400 06/20/2024 MRN#: 27391 06/20/2024 MRN#: 27400 06/26/2024 MRN#: 27400 06/24/2024 MRN#: 27391 06/24/2025 MRN#: 27400 6. An interview on 07/17/2025 at 12:30 pm in the lab, the technical consultant (indicated on the CMS 209 form) confirmed the above findings. ****This is a repeated deficiency**** Key: C=Celsius F=Fahrenheit CMS=Center for Medicare and Medicaid Services

D6053

TECHNICAL CONSULTANT RESPONSIBILITIES
CFR(s): 493.1413(b)(9)

(b)(9) 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 laboratory's CMS 209 form, the personnel's competency assessment records, and confirmed in an interview, the technical consultant failed to evaluate and document at least twice of competency assessments during the first year for 1 of 6 TP performing moderate complexity testing. The findings were: 1. Review of the laboratory's CMS 209 form, Laboratory Personnel Report (CLIA), signed by the laboratory on 07/13/2025, revealed the laboratory identified 6 TP performing moderate complexity testing. 2. Review of the laboratory's competency assessment records revealed the technical consultant failed to evaluate and document at least twice of competency assessments during the first year for 1 of 6 TP performing moderate complexity testing. TP#5 Hired date: 08/01/2023 Missing 1st annual competency assessment. 3. An interview on 07/17/2025 at 11:30 am in the lab, the technical consultant (indicated on the CMS 209 form) confirmed the above findings. Key: CMS=Center of Medicare and Medicaid Services TP=Testing personnel

D6061

CLINICAL CONSULTANT RESPONSIBILITIES
CFR(s): 493.1419(c)

(c) Ensure that reports of test results include pertinent information required for specific patient interpretation; and

This STANDARD is not met as evidenced by:
Based on the review of the laboratory's validation records for DxH 520 hematology analyzer, random review of the patient CBC final reports, and confirmed in an interview, the clinical consultant failed to ensure the correct reference ranges were on

the CBC patient final reports for 7 of 7 patients reviewed. The findings were: 1. Review the laboratory's validation records for Beckman Coulter DxH 520 hematology analyzer (SN:BG010034) , signed by the laboratory director on 12/12/2023, revealed DxH 520 reference ranges were verified as follows. WBC $3.71-10.67 \times 10^3$ ul RBC $3.87-5.68 \times 10^6$ ul HGB 12.00-16.75 g/dl Platelet $150.5-366.8 \times 10^3$ uL 2. An interview on 07/17/2025 at 12:45 pm in the lab, the technical consultant (indicated on the CMS 209 form) confirmed 4 direct measured analytes were WBC, RBC, HGB, and Platelets on DxH 520. All other analytes were calculated based on those 4 analytes. 3. Random review of the laboratory's CBC patient final reports performed on DxH 520 revealed 7 of 7 patient final report direct measured analytes reference ranges were different from the reference ranges obtained from validation records. CBC performed date: 01/22/2024 MRN#: 27301 Reference ranges on the report: WBC $3.77-11.03 \times 10^3$ ul RBC $3.83-5.06 \times 10^6$ ul HGB 11.59-15.11 g/dl Platelet $169.1-368.3 \times 10^3$ uL CBC performed date: 06/03/2024 MRN#: 26884 Reference ranges on the report: WBC $3.77-11.03 \times 10^3$ ul RBC $3.83-5.06 \times 10^6$ ul HGB 11.59-15.11 g/dl Platelet $169.1-368.3 \times 10^3$ uL CBC performed date: 06/02/2025 MRN#: 27579 Reference ranges on the report: WBC $3.53-9.52 \times 10^3$ ul RBC $4.33-5.72 \times 10^6$ ul HGB 12.55-16.99 g/dl Platelet $146.5-351.5 \times 10^3$ uL CBC performed date: 06/04/2025 MRN#: 27539 Reference ranges on the report: WBC $3.53-9.52 \times 10^3$ ul RBC $4.33-5.72 \times 10^6$ ul HGB 12.55-16.99 g/dl Platelet $146.5-351.5 \times 10^3$ uL CBC performed date: 06/09/2025 MRN#: 27595 Reference ranges on the report: WBC $3.77-11.03 \times 10^3$ ul RBC $3.83-5.06 \times 10^6$ ul HGB 11.59-15.11 g/dl Platelet $169.1-368.3 \times 10^3$ uL CBC performed date: 06/23/2025 MRN#: 27607 Reference ranges on the report: WBC $3.77-11.03 \times 10^3$ ul RBC $3.83-5.06 \times 10^6$ ul HGB 11.59-15.11 g/dl Platelet $169.1-368.3 \times 10^3$ uL CBC performed date: 07/01/2025 MRN#: 27555 Reference ranges on the report: WBC $3.53-9.52 \times 10^3$ ul RBC $4.33-5.72 \times 10^6$ ul HGB 12.55-16.99 g/dl Platelet $146.5-351.5 \times 10^3$ uL 4. An interview on 07/17/2025 at 2:05 pm in the lab, the technical consultant (indicated on the CMS 209 form) confirmed the above findings. Key: CBC=Complete Blood Count WBC=White blood cell RBC=Red blood cell HGB=Hemoglobin CMS=Center of Medicare and Medicaid Services