Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	14D2162934	10/05/2021
Name of Provider or Supplier	**Street Address, City, State**	
Burbank Rehabilitation Center	5400 W 87th St, Burbank, IL	

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
D5211	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(a) The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part. This STANDARD is not met as evidenced by: Based on record review, proficiency testing (PT) reports, and interview, the laboratory failed to review and evaluate the results obtained on proficiency testing performed in Blood Gas Chemistry during 2021. Findings include: 1. The College of American Pathologists (CAP) PT programs' reports for the years 2019 through 2021 and procedures manual were reviewed. 2. CAP- PT reports revealed the laboratory received the following scores for Event #2, 2021: *PH BLOOD GAS = 100% *P02 BLOOD GAS = 100% *PCO2 BLOOD GAS = 80% 3. The laboratory failed to follow its PT policy and implement procedures to review and evaluate all PT results received. 4. On a Recertification survey 10/05/2021 at 1:20 PM, the laboratory director confirmed the above findings.
D5801	TEST REPORT CFR(s): 493.1291(a) The laboratory must have an adequate manual or electronic system(s) in place to ensure test results and other patient-specific data are accurately and reliably sent from the point of data entry (whether interfaced or entered manually) to final report destination, in a timely manner. This includes the following: (a)(1) Results reported from calculated data. (a)(2) Results and patient-specific data electronically reported to network or interfaced systems. (a)(3) Manually transcribed or electronically transmitted results and patient-specific information reported directly or upon receipt from outside referral laboratories, satellite or point-of-care testing locations.

	This STANDARD is not met as evidenced by: Based on record review, lack of documentation, and interview, the laboratory failed to accurately and reliably enter test results into the patient's electronic medical records (EMR), for two out of six patients. Findings include: 1. The laboratory's procedure manual, six randomly selected patients' i-STAT test records from 12/2019 to 09/2021, and patients' electronic records were reviewed. 2. The patients' results and electronic medical records (EMR) reports revealed that two out of four patients' results were entered incorrectly into the patients chart. 3. The laboratory failed to ensure the information from test results were accurately and reliably entered into the patients' EMR. 4. On a Recertification survey 10/05/2021 at 1:20 PM, the laboratory director confirmed the above findings.
D5891	POSTANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1299(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess and, when indicated, correct problems identified in the postanalytic systems specified in 493.1291. This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory failed to establish written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in transcribing patients' results, affecting two out six patients. Findings include: 1. The laboratory's procedures manual, patients' electronic records, and patients' test logs were reviewed. 2. Review of six patients' reports revealed two out of six patients test results were transcribed incorrectly into their electronic medical record (EMR). See D5801. 3. The procedures manual failed to establish a policy and procedure for monitoring and preventing transcription errors when reporting patient results into EMR. 4. On a Recertification survey 10/05/2021 at 1:20 PM, the laboratory director confirmed the above findings.
D6046	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8) (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. This STANDARD is not met as evidenced by: Based on record review, the Laboratory Personnel Report (CMS 209), and interview, the technical consultant (TC) failed to evaluate the competency of all testing personnel and assure that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently for two out of two testing personnel (TP) performing Blood Gas Chemistry testing. Findings: 1. The CMS 209, personnel records, and the laboratory's Performance/Competency Testing policies were reviewed. 2. The Competency Assessment policy states the following TC responsibility: "Evaluate and document testing personnel performance at least semiannually for the first year and annually there after." 3. The personnel records and CMS 209 revealed from 7-8-20 to 7-7-2021 no annual competency assessments was performed for two of two TP as outlined in the laboratory procedure. 4. On a

	Recertification survey 10/05/2021 at 1:20 PM, the laboratory director confirmed the above findings.
D6056	CLINICAL CONSULTANT CFR(s): 493.1415 The laboratory must have a clinical consultant who meets the qualification requirements of 493.1417 of this part and provides clinical consultation in accordance with 493.1419 of this part. This CONDITION is not met as evidenced by: Based on record review, Clinical Laboratory Improvement Amendments (CLIA) application (CMS 116), the Laboratory Personnel Report (CMS 209), and interview, the laboratory failed to have an employee who meets the qualification requirements and provide clinical consultation (CC) for the Blood Gas testing performed (D6057), affecting 159 patients.
D6057	CLINICAL CONSULTANT QUALIFICATIONS CFR(s): 493.1417 The clinical consultant must be qualified to consult with and render opinions to the laboratory's clients concerning the diagnosis, treatment and management of patient care. The clinical consultant must-- (a) Be qualified as a laboratory director under 493. 1405(b)(1), (2), or (3)(i); or (b) Be a doctor of medicine, doctor of osteopathy or doctor of podiatric medicine and possess a license to practice medicine, osteopathy or podiatry in the State in which the laboratory is located. This STANDARD is not met as evidenced by: Based on record review, the Laboratory Personnel Report (CMS 209), Clinical Laboratory Improvement Amendments (CLIA) application (CMS 116), and interview, the laboratory failed to employ a clinical consultant (CC) for the Blood Gas testing performed in the laboratory. Findings: 1. The CMS 209, personnel files, and CMS 116 application signed by the laboratory director (LD) on 10/05/2021 were reviewed. 2. The CMS 209 was reviewed and found the laboratory director (LD) failed to designate and ensure employment of a qualified CC for the laboratory. 3. The personnel files revealed that since June 06, 2020, the laboratory failed to have a qualified CC. 4. Review of the CMS 116 showed the laboratory performed 159 patients' tests annually. 5. On a Recertification survey 10/05/2021 at 1:20 PM, the LD confirmed the above findings.