Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D0490653	(X3) Date Survey Completed 12/07/2023
Name of Provider or Supplier Mcgovern Allergy & Asthma Clinic, Pa	**Street Address, City, State** 4710 Bellaire Blvd Ste 200, Bellaire, 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	An announced survey for initial certification was performed on 12/7/23. The laboratory was found out of compliance with the CLIA regulations. The conditions not met were: D2000 - 42 C.F.R. 493.801 Condition: Enrollment and testing of [proficiency testing] samples; D6063 - 42 C.F.R. 493.1421 Condition: Laboratories performing moderate complexity testing; testing personnel;
D2000	ENROLLMENT AND TESTING OF SAMPLES CFR(s): 493.801 Each laboratory must enroll in a proficiency testing (PT) program that meets the criteria in subpart I of this part and is approved by HHS. The laboratory must enroll in an approved program or programs for each of the specialties and subspecialties for which it seeks certification. The laboratory must test the samples in the same manner as patients' specimens. For laboratories subject to 42 CFR part 493 published on March 14, 1990 (55 FR 9538) prior to September 1, 1992, the rules of this subpart are effective on September 1, 1992. For all other laboratories, the rules of this subpart are effective January 1, 1994. This CONDITION is not met as evidenced by: Based on a review of the laboratory's AAB- Medical Laboratory Evaluation proficiency testing records and staff interview, the laboratory failed to have documentation of participating in a proficiency testing program for three of three regulated analytes included in the Complete Blood Count (CBC) in 2023. (Refer to D2004)
D2004	ENROLLMENT CFR(s): 493.801(a)(3) For each specialty, subspecialty and analyte or test, participate in one approved proficiency testing program or programs, for one year before designating a different

	program and must notify CMS before any change in designation; This STANDARD is not met as evidenced by: Based on a review of the laboratory's AAB- Medical Laboratory Evaluation proficiency testing records and staff interview, the laboratory failed to have documentation of participating in a proficiency testing program for three of three regulated analytes included in the Complete Blood Count (CBC) in 2023. Findings include: 1. A review of the laboratory's AAB- Medical Laboratory Evaluation records revealed the laboratory failed to provide documentation of participating in a proficiency testing program for the following analytes included in the CBC for 2023: - Red Blood Cell - Hematocrit - Platelet 2. In an interview on 12/7/23 at 9:35 a.m. in the conference room, after review of the records, the technical consultant (as indicated on the CMS 209 form) confirmed the above findings.
D5411	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a) 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. This STANDARD is not met as evidenced by: Based on a review of the Sysmex XP-300 Instructions for Use, a review of the laboratory's patient test records, and staff interview, the laboratory failed to ensure patient's results were rerun when analytes were flagged for seven of twenty patient test records reviewed from November 2023. Findings include: 1. A review of the Sysmex XP-300 Instructions for Use (AU553517, 10/2015) revealed the following: "When histogram flags are displayed, perform analysis again." 2. A review of patient's test records from November 2023 the following 7 patients were tested on the Sysmex XP-300 hematology analyzer and the laboratory failed to have documentation of rerunning the patient specimen: - Patient ID: 268981 Tested on 11/1/23 AG flag on Platelet count - Patient ID:265413 Tested on 11/2/23 AG flag on Platelet count - Patient ID: 251394 Tested on 11/6/23 AG flag on Platelet count - Patient ID: 275697 Tested on 11/8/23 AG flag on Platelet count - Patient ID: 268708 Tested on 11/27/23 AG flag on Platelet count - Patient ID: 266855 Tested on 11/29/23 AG flag on Platelet count - Patient ID: 266002 Tested on 11/30/23 AG flag on Platelet count 3. In an interview on 12/7/23 at 10:40 a.m. in the conference room, after review of the records, the technical consultant (as indicated on the CMS 209 form) confirmed the above findings.
D6051	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8)(v) The procedures for evaluation of the competency of the staff must include, but are not limited to assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples. This STANDARD is not met as evidenced by: Based on a review of the laboratory's annual competency assessments and staff

	interview, the technical consultant failed to assess test performance through testing previous specimens, blind test samples, or external proficiency testing samples for one of one annual competency assessment performed for Complete Blood Count (CBC) testing on the Sysmex XP-300 hematology analyzer in 2023. Findings include: 1. A review of the laboratory's annual competency assessments performed in 2023 revealed the technical consultant failed to assess test performance through testing previous specimens, blind test samples, or external proficiency testing samples for testing person #1 for CBC testing on the Sysmex XP-300 hematology analyzer. 2. In an interview on 12/7/23 at 9:25 a.m. in the conference room, after review of the records, the technical consultant (as indicated on the CMS 209 form) confirmed the above findings.
D6052	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8)(vi) The procedures for evaluation of the competency of the staff must include, but are not limited to assessment of problem solving skills. This STANDARD is not met as evidenced by: Based on a review of the laboratory's annual competency assessments and staff interview, the technical consultant failed assess problem solving skills for one of one annual competency assessment performed for Complete Blood Count (CBC) testing on the Sysmex XP-300 hematology analyzer in 2023. Findings include: 1. A review of the laboratory's annual competency assessments performed in 2023 revealed the technical consultant failed to assess problem solving skills for testing person #1 for CBC testing on the Sysmex XP-300 hematology analyzer. 2. In an interview on 12/7 /23 at 9:25 a.m. in the conference room, after review of the records, the technical consultant (as indicated on the CMS 209 form) confirmed the above findings.
D6063	LABORATORY TESTING PERSONNEL CFR(s): 493.1421 The laboratory must have a sufficient number of individuals who meet the qualification requirements of 493.1423, to perform the functions specified in 493. 1425 for the volume and complexity of tests performed. This CONDITION is not met as evidenced by: Based on review of the laboratory's personnel records and staff interview, the laboratory failed to have documentation of education for one of one testing person to perform moderate complexity testing in 2023. (Refer to D6065)
D6065	TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1423(b)(1)(2)(3)(4)(i) (b) Meet one of the following requirements: (b)(1) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located or have earned a doctoral, master's, or bachelor's degree in a chemical, physical, biological or clinical laboratory science, or medical technology from an accredited institution; or (b)(2) Have earned an associate degree in a chemical, physical or biological science or medical laboratory technology from an accredited institution; or (b)(3) Be a high school graduate or equivalent and have

	successfully completed an official military medical laboratory procedures course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); or (b)(4)(i) Have earned a high school diploma or equivalent; and This STANDARD is not met as evidenced by: Based on a review of the laboratory's submitted CMS 209 form, the laboratory's personnel records, and staff interview, the laboratory failed to have documentation of education for one of one testing person to qualify them to perform moderate complexity testing on the Sysmex XP-300 hematology analyzer in 2023. Findings include: 1. A review of the CMS 209 form revealed one testing person who performed moderate complexity testing on the Sysmex XP-300 hematology analyzer. 2. A review of the laboratory's personnel records revealed the laboratory failed to have documentation of education for testing person #1. 3. In an interview on 12/7/23 at 9: 15 a.m. in the conference room, after review of the records, the technical consultant (as indicated on the CMS 209 form) confirmed the above findings.