Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D0490653	12/13/2024
Name of Provider or Supplier	**Street Address, City, State**	
Mcgovern Allergy & Asthma Clinic, Pa	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	Based on a proficiency testing desk review survey performed on December 11, 2024, the laboratory was found to be out of compliance based on the following CONDITION LEVEL DEFICIENCIES: D2016 - 42 C.F.R. 493.803 Condition: Successful participation D6000 - 42 C.F.R. 493.1403 Condition: Laboratory Director, moderate complexity
D2016	SUCCESSFUL PARTICIPATION CFR(s): 493.803(a)(b)(c) (a) Each laboratory performing nonwaived testing must successfully participate in a proficiency testing program approved by CMS, if applicable, as described in subpart I of this part for each specialty, subspecialty, and analyte or test in which the laboratory is certified under CLIA. (b) Except as specified in paragraph (c) of this section, if a laboratory fails to participate successfully in proficiency testing for a given specialty, subspecialty, analyte or test, as defined in this section, or fails to take remedial action when an individual fails gynecologic cytology, CMS imposes sanctions, as specified in subpart R of this part. (c) If a laboratory fails to perform successfully in a CMS-approved proficiency testing program, for the initial unsuccessful performance, CMS may direct the laboratory to undertake training of its personnel or to obtain technical assistance, or both, rather than imposing alternative or principle sanctions except when one or more of the following conditions exists: (1) There is immediate jeopardy to patient health and safety. (2) The laboratory fails to provide CMS or a CMS agent with satisfactory evidence that it has taken steps to correct the problem identified by the unsuccessful proficiency testing performance. (3) The laboratory has a poor compliance history. This CONDITION is not met as evidenced by: Based on review of the Certification and Survey Provider Enhanced Reporting (CASPER) Report 155 Individual Laboratory Profile and American Association of Bioanalysts/Medical Laboratory Evaluation proficiency reports, the laboratory failed

	to achieve satisfactory performance for two of two consecutive testing events for the analytes RBC, HCT, HGB, WBC Count, and Platelets, resulting in an initial unsuccessful performance. Refer to D2130.
D2130	HEMATOLOGY CFR(s): 493.851(f) Failure to achieve satisfactory performance for the same analyte in two consecutive events or two out of three consecutive testing events is unsuccessful performance. This STANDARD is not met as evidenced by: Based on review of the Certification and Survey Provider Enhanced Reporting (CASPER) Report 155 Individual Laboratory Profile and American Association of Bioanalysts/Medical Laboratory Evaluation proficiency reports, the laboratory failed to achieve satisfactory performance for two of two consecutive testing events in 2024 for the analytes RBC, HCT, HGB, WBC Count, and Platelets. The findings included: 1. Based on review of the Certification and Survey Provider Enhanced Reporting (CASPER) Report 155 Individual Laboratory Profile report, the laboratory received the following unsatisfactory performances for the analytes RBC, HCT, HGB, WBC Count, and Platelets for two consecutive testing events: 2024 AAB/MLE 2nd event 0% 2024 AAB/MLE 3rd event 0% 2. Based on review of the American Association of Bioanalysts/Medical Laboratory Evaluation proficiency reports, the laboratory received the following unsatisfactory performances for the analytes RBC, HCT, HGB, WBC Count, and Platelets for two consecutive testing events: 2024 AAB/MLE 2nd event 0% 2024 AAB/MLE 3rd event 0% Key: RBC = Red Blood Cell HCT = Hematocrit HGB = Hemoglobin WBC Count = White Blood Cell Count
D2131	HEMATOLOGY CFR(s): 493.851(g) Failure to achieve an overall testing event score of satisfactory performance for two consecutive testing events or two out of three consecutive testing events is unsuccessful performance. This STANDARD is not met as evidenced by: Based on a review of the Certification and Survey Provider Enhanced Reporting (CASPER) Report 155 Individual Laboratory Profile and American Association of Bioanalysts/Medical Laboratory Evaluation proficiency reports, the laboratory failed to achieve satisfactory performance for two of two consecutive testing events for the Hematology specialty in 2024. The findings included: 1. Based on a review of the Certification and Survey Provider Enhanced Reporting (CASPER) Report 155 Individual Laboratory Profile report, the laboratory received the following unsatisfactory performances for the Hematology specialty for 2 consecutive testing events: 2024 AAB/MLE 2nd event 0% 2024 AAB/MLE 3rd event 0% 2. Based on review of the American Association of Bioanalysts/Medical Laboratory Evaluation proficiency reports, the laboratory received the following unsatisfactory performances for the Hematology specialty for 2 consecutive testing events: 2024 AAB/MLE 2nd event 0% 2024 AAB/MLE 3rd event 0%
D6000	MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403

	The laboratory must have a director who meets the qualification requirements of 493.1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart. This CONDITION is not met as evidenced by: Based on desk review of the Certification and Survey Provider Enhanced Reporting (CASPER) Report 155 Individual Laboratory Profile and American Association of Bioanalysts/Medical Laboratory Evaluation proficiency reports, the laboratory director failed to provide overall management and direction of the laboratory services. Refer to D6016.
D6016	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(i) 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)(i) Ensure that the proficiency testing samples are tested as required under Subpart H of this part; This STANDARD is not met as evidenced by: Based on desk review of the Certification and Survey Provider Enhanced Reporting (CASPER) Report 155 Individual Laboratory Profile and American Association of Bioanalysts/Medical Laboratory Evaluation proficiency reports, the laboratory director failed to ensure successful participation in a HHS approved proficiency testing program for two of two consecutive testing events for the analytes RBC, HCT, HGB, WBC Count, and Platelets, resulting in an initial unsuccessful performance. Refer to D2130.