Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	14D0419924	12/04/2024
Name of Provider or Supplier	**Street Address, City, State**	
Doctors General Laboratory	59 Ogden Ave, Clarendon Hills, 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
D5213	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(b)(1) The laboratory must verify the accuracy of any analyte or subspecialty without analytes listed in subpart I of this part that is not evaluated or scored by a CMS-approved proficiency testing program. This STANDARD is not met as evidenced by: Based on review of laboratory policies and procedures, laboratory records, American Proficiency Institute (API) proficiency testing (PT) records, lack of documentation, and interview with the laboratory owner; the laboratory failed to ensure accuracy of 55 of 55 analytes not evaluated by the PT provider for seven of seven PT events in the specialties of diagnostic immunology, hematology, microbiology, and chemistry in 2023 and 2024. Findings include: 1. Review of laboratory policies and procedures revealed the policy titled, "Proficiency Testing", which stated, under "Receipt of Survey Results", "For all flagged results, review the QC for that day. Attempt to explain all flagged results." 2. Review of API comparative evaluation summaries for the following PT events of 2023 and 2024 revealed the following un-graded PT samples: PT Event: Analyte : Sample: 2023 Event 3 C-Reactive Protein CRP-05 2024 Event 1 Bilirubin, total CH-02 2024 Event 1 Bilirubin, total CH-03 2024 Event 1 Bilirubin, total CH-05 2024 Event 1 TMS* UR-01 2024 Event 1 Vancomycin UR-01 2024 Event 2 Urobilinogen UA-04 2024 Event 2 Iron, total CH-08 2024 Event 2 Iron, total CH-08 2024 Event 2 Ciprofloxacin UR-06 2024 Event 3 Azithromycin UR-11 2024 Event 3 CTX-M Group 1** UTI-11 2024 Event 3 CTX-M Group 1** UTI-13 2024 Event 3 CTX-M Group 1** UTI-14 2024 Event 3 CTX-M Group 1** UTI-15 2024 Event 3 CTX-M Group 2** UTI-11 2024 Event 3 CTX-M Group 2** UTI-13 2024 Event 3 CTX-M Group 2** UTI-14 2024 Event 3 CTX-M Group 2** UTI-15 2024 Event 3 ErmA** UTI-12 2024 Event 3 ErmA** UTI-13 2024 Event 3 ErmA** UTI-14 2024 Event 3 ErmB** UTI-11 2024 Event 3 ErmB** UTI-13 2024 Event 3 ErmB** UTI-14 2024 Event 3 ErmC** UTI-13 2024 Event 3 ErmC** UTI-14 2024

	Event 3 mecA** UTI-11 2024 Event 3 mecA** UTI-12 2024 Event 3 mecA** UTI-13 2024 Event 3 mecA** UTI-14 2024 Event 3 mecA** UTI-15 2024 Event 3 NDM** UTI-11 2024 Event 3 NDM** UTI-13 2024 Event 3 NDM** UTI-14 2024 Event 3 NDM** UTI-15 2024 Event 3 OXA** UTI-11 2024 Event 3 OXA** UTI-13 2024 Event 3 OXA** UTI-14 2024 Event 3 OXA** UTI-15 2024 Event 3 qnr** UTI-11 2024 Event 3 qnr** UTI-13 2024 Event 3 qnr** UTI-14 2024 Event 3 qnr** UTI-15 2024 Event 3 qnrB** UTI-11 2024 Event 3 qnrB** UTI-13 2024 Event 3 qnrB** UTI-14 2024 Event 3 qnrB** UTI-15 2024 Event 3 Tet M** UTI-12 2024 Event 3 Tet M** UTI-13 2024 Event 3 Tet M** UTI-14 2024 Event 3 VIM** UTI-11 2024 Event 3 VIM** UTI-13 2024 Event 3 VIM** UTI-14 2024 Event 3 VIM** UTI-15 *TMS = Trimethoprim/Sulfamethoxazole **Molecular Resistance Markers 3. Review of laboratory records found no documented review of the ungraded PT analytes in the specialties of diagnostic immunology, hematology, microbiology, and chemistry in 2023 and 2024. 4. Interview with the laboratory owner on 12/04/2024, at 3:44 pm, confirmed the laboratory failed to ensure accuracy of analytes not evaluated by the PT provider for seven of seven applicable PT events.
D5400	ANALYTIC SYSTEMS CFR(s): 493.1250 Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in 493.1251 through 493.1283, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub.7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the analytic systems and correct identified problems as specified in 493.1289 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: Based on review of laboratory policies and procedures, laboratory records, lack of documentation, and interviews with the laboratory owner and technical supervisor (TS) #2; the laboratory failed to ensure negative and positive control materials were tested each day of patient testing for four of four patients reviewed in the specialty of microbiology (See D5449).
D5449	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(ii)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- At least once a day patient specimens are assayed or examined perform the following for-- Each qualitative procedure, include a negative and positive control material; (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of laboratory policies and procedures, laboratory records, lack of documentation, and interviews with the laboratory owner and technical supervisor (TS) #2; the laboratory failed to ensure negative and positive control materials were tested each day of patient testing for four of four patients reviewed in the specialty of microbiology from the beginning of 2023 to the date of survey, 12/04/2024, affecting 3,603 patients. Findings include: 1. Review of laboratory policies and procedures revealed the policy titled, "Quality Control Program and Policy", which stated, under

	"[Section] IV", "Positive and negative controls are used for each run of patients ...." 2. Review of laboratory policies and procedures revealed the procedure titled, "Analysis of Urinary Tract Microbiota by PCR [Polymerase Chain Reaction]" found the following pathogens and antibiotic resistance markers (ABRs) tested on the Urinary Tract Microbiota (UTM) PCR Panel: Pathogens: Candida albicans Citrobacter freundii Enterobacter aerogenes Enterobacter cloacae Enterococcus faecalis Enterococcus faecium Escherichia coli Klebsiella oxytoca Klebsiella pneumonia Morganella morganii Proteus mirabilis Proteus vulgaris Providencia stuartii Pseudomonas aeruginosa Staphylococcus saprophyticus Streptococcus agalactiae (Group B) Chlamydia trachomatis Neisseria gonorrhoeae Trichomonas vaginalis Gardnerella vaginalis ABRs: NDM Beta-lactam resistance VIM Beta-lactam resistance Methicillin resistance Tetracycline resistance Fox Beta-lactam resistance Erythromycin A, B, C resistances GES Beta-lactam resistance Quinolone resistance Quinolone B resistance CTX-M Group 1, 2 resistances Vancomycin resistance CTX-M Group 8/25, Group 9 resistances Oxacillinase resistance Carbapenem resistance Extended resistance 3. Review of laboratory quality control records for four of four patient testing dates review for UTM PCR Panel found positive and negative control materials were not utilized on each day of patient testing. Date: Patient: Positive Control: Negative Control: Extraction Control: 01/13/2023 257352 Not performed Performed Performed 09/06/2023 257894 Not performed Performed Performed 02/26 /2024 484288 Not performed Not Performed Not Performed 10/22/2024 499986 Not performed Not Performed Not Performed 4. Interviews with the laboratory owner and TS #2 on 12/04/2024, at 2:39 pm, confirmed the laboratory failed to ensure negative and positive control materials were tested each day of patient testing. 5. Interview with the laboratory owner on 12/04/2024, at 3:56 pm, revealed 3,603 UTM PCR Panels had been performed from the beginning of 2023 through the date of survey, 12 /04/2024.