Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	01D0968763	01/08/2025
Name of Provider or Supplier	**Street Address, City, State**	
Regency Laboratory	5320 Highway 90 Service Road, Mobile, AL	

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	The following deficiencies are a result of desk review of proficiency testing scores obtained from the national database and verified with the laboratory's proficiency testing provider, AAB-MLE (AAB-Medical Laboratory Evaluation). The laboratory was found to be out of compliance with CONDITION LEVEL DEFICIENCIES, as follows: D2016 - 42 C.F.R. 493.803 Condition: Successful participation [proficiency testing] D6000 - 42 C.F.R. 493.1403 Condition: Laboratories performing moderate complexity testing; laboratory director .
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 off-site proficiency testing (PT) desk reviews of the CASPER Reports

	0153D and 0155D (Individual Laboratory Profiles from the Centers of Medicare and Medicaid Services [CMS]), review of emails from the AAB-MLE (AAB-Medical Laboratory Evaluation), and a phone interview with the Technical Consultant, the laboratory failed to successfully participate in proficiency testing in the Specialties of Chemistry and Endocrinology. The laboratory failed to notify AAB-MLE within the required timeframes testing had ceased on the Chemistry analyzer, and received failing scores of 0% due to "Failure to Participate". This occurred two consecutive PT events in 2024, resulting in initial unsuccessful proficiency testing performance. Refer to D2089 and D2100. .
D2089	ROUTINE CHEMISTRY CFR(s): 493.841(c) (c) Failure to participate in a testing event is unsatisfactory performance and results in a score of 0 for the testing event. Consideration may be given to those laboratories failing to participate in a testing event only if-- (1) Patient testing was suspended during the time frame allotted for testing and reporting proficiency testing results; (2) The laboratory notifies the inspecting agency and the proficiency testing program within the time frame for submitting proficiency testing results of the suspension of patient testing and the circumstances associated with failure to perform tests on proficiency testing samples; and (3) The laboratory participated in the previous two proficiency testing events. This STANDARD is not met as evidenced by: Based on off-site proficiency testing (PT) desk reviews of the CASPER Reports 0153D and 0155D (Individual Laboratory Profiles from the Centers of Medicare and Medicaid Services [CMS]), emails from AAB-MLE (AAB-Medical Laboratory Evaluation), and a phone interview with the Technical Consultant, the laboratory failed to notify the PT provider within the required time frame for submitting proficiency testing results of the suspension of patient testing in the Specialty of Chemistry. This occurred two consecutive PT events, resulting in initial unsuccessful performance. The findings included: 1. Based on review of the CASPER Reports 153D and 155D, Individual Laboratory Profile reports, the laboratory received failing scores of 0% for 2024-Event M2 and 2024-Event M3 in the Specialty of Chemistry for all analytes, as follows: ALT (Alanine Aminotransferase), Albumin, Alkaline Phosphorase, AST (Aspartate Aminotransferase), Total Bilirubin, Calcium, CL (Chloride), Total Cholesterol, HDL (High Density Lipoprotein) Cholesterol, CK (Creatine Kinase), Creatinine, Glucose, LDH (Lactate Dehydrogenase), K (Potassium), NA (Sodium), Total Protein, Triglycerides, BUN (Blood Urea Nitrogen), and Uric Acid. 2. During a phone interview on 1/6/2025 at 9:20 AM, the Technical Consultant stated the laboratory had ceased all testing on the Chemistry analyzer in 2024, and his AAB-MLE evaluation did not show the 0% scores for Chemistry. When asked if the laboratory had notified AAB-MLE Chemistry testing had been terminated, the TC stated he was not sure, and he would contact the PT provider. 3. A review of an email to the CLIA Alabama State Agency on 1/6/2024 at 10:20 AM from AAB-MLE revealed, "Regency Lab (CLIA# 01D0968763) did not report any online comments for 2024 for stopped testing on the Chemistry Module (CAT# 810) regulated analytes, nor do we find any written documentation that they stopped patient testing on those analytes either. ...". 4. The above email further stated AAB-MLE would correct the record if the laboratory provided written documentation proving

	notification. However, as of 1/8/2024 at 9:52 AM, via email AAB-MLE stated, "...we do not show any additional documentation of ceased testing for M2 or M3 events for the chemistry analytes...". .
D2100	ENDOCRINOLOGY CFR(s): 493.843(c) (c) Failure to participate in a testing event is unsatisfactory performance and results in a score of 0 for the testing event. Consideration may be given to those laboratories failing to participate in a testing event only if-- (1) Patient testing was suspended during the time frame allotted for testing and reporting proficiency testing results; (2) The laboratory notifies the inspecting agency and the proficiency testing program within the time frame for submitting proficiency testing results of the suspension of patient testing and the circumstances associated with failure to perform tests on proficiency testing samples; and (3) The laboratory participated in the previous two proficiency testing events. This STANDARD is not met as evidenced by: Based on off-site proficiency testing (PT) desk reviews of the CASPER Reports 0153D and 0155D (Individual Laboratory Profiles from the Centers of Medicare and Medicaid Services [CMS]), emails from AAB-MLE (AAB-Medical Laboratory Evaluation), and a phone interview with the Technical Consultant, the laboratory failed to notify the PT provider within the required time frame for submitting proficiency testing results of the suspension of patient testing for the analyte T4 (Total Thyronine) in the Specialty of Endocrinology. This occurred two consecutive PT events, resulting in initial unsuccessful performance for T4 and the Specialty of Endocrinology. The findings included: 1. Based on review of the CASPER Reports 153D and 155D, Individual Laboratory Profile reports, the laboratory received failing scores for two consecutive PT events, as follows: A. 2024-Event M2: Total T4 with a score of 0%, resulting in a failing score of 53% for the Specialty of Endocrinology; and B. 2024-Event M3: Total T4 with a score of 0%, resulting in a failing score of 66% for the Specialty of Endocrinology 2. During a phone interview on 1/6/2025 at 9: 20 AM, the Technical Consultant stated the laboratory had ceased all testing in 2024 on the Chemistry analyzer (which included Total T4), and further stated his AAB-MLE evaluation did not show the 0% scores for Total T4. When asked if the laboratory had notified AAB-MLE Total Thyroxine testing had been terminated, the TC stated he was not sure, and he would contact the PT provider. 3. A review of an email to the CLIA Alabama State Agency on 1/6/2024 at 10:20 AM from AAB-MLE revealed, "Regency Lab (CLIA# 01D0968763) did not report any online comments for 2024 for stopped testing on the Chemistry Module (CAT# 810) regulated analytes [this module included Endocrinology, a subspecialty of Chemistry], nor do we find any written documentation that they stopped patient testing on those analytes either. ...". 4. The above email further stated AAB-MLE would correct the record if the laboratory provided written documentation proving notification. However, as of 1/8 /2024 at 9:52 AM, via email AAB-MLE stated, "...we do not show any additional documentation of ceased testing for M2 or M3 events ... or for Total T4 [Thyroxine] specifically." .
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 off-site proficiency testing (PT) desk reviews of the CASPER Reports 0153D and 0155D (Individual Laboratory Profiles from the Centers of Medicare and Medicaid Services [CMS]), emails from AAB-MLE (AAB-Medical Laboratory Evaluation), and a phone interview with the Technical Consultant, the laboratory director failed to ensure successful participation in an HHS approved proficiency testing program. Refer to D6017. .
D6017	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(ii) (e)(4)(ii) Ensure that results are returned within the timeframes established by the proficiency testing program; This STANDARD is not met as evidenced by: Based on off-site proficiency testing (PT) desk reviews of the CASPER Reports 0153D and 0155D (Individual Laboratory Profiles from the Centers of Medicare and Medicaid Services [CMS]), emails from AAB-MLE (AAB-Medical Laboratory Evaluation), and a phone interview with the Technical Consultant, the laboratory director failed to ensure the laboratory notified AAB-MLE within the required timeframes testing had ceased on the Chemistry analyzer. The laboratory received failing scores of 0% due to "Failure to Participate" for two consecutive 2024 AAB-MLE PT events, resulting in initial unsuccessful participation. Refer to D2089 and D2100. SURVEYOR ID# 32558 Licensure and Certification Surveyor