

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 49D0233214	(X3) Date Survey Completed 05/07/2025
Name of Provider or Supplier Memorial Family Care, Inc	Street Address, City, State 501 Rison Street Suite 120, Danville, VA	
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 unannounced, off-site CLIA proficiency testing (PT) desk review was conducted for Memorial Family Care, INC on May 6, 2025 by the Virginia Department of Health's Office of Licensure and Certification. The survey concluded with an interview with the laboratory's technical consultant on 5/7/25. The laboratory was surveyed under 42 CFR part 493 CLIA Requirements. The following deficiencies are a result of the PT desk review of scores obtained from the national database and verified with the proficiency testing company. The facility was found to be out of compliance with the conditions of the CLIA program. The following CONDITION LEVEL DEFICIENCIES were found to be out of compliance: D2016 - 42 CFR. 493.803 Condition: Successful Participation D6000 - 42 C.F.R. 493.1403 Condition: Laboratories performing moderate complexity testing- Laboratory Director
D2016	<p>SUCCESSFUL PARTICIPATION CFR(s): 493.803(a)(b)(c)</p> <p>(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.</p>

This CONDITION is not met as evidenced by:
Based on an off-site desk review of the Center for Medicaid and Medicare Services (CMS) CASPER 0155 report, the laboratory's proficiency testing (PT) records and interview, the laboratory failed to attain a score of at least eighty percent of acceptable responses for Red Blood Cell Count on two consecutive hematology testing events, reviewed on May 6, 2025, resulting in an initial unsuccessful PT performance. Refer to D2130.

D2130

HEMATOLOGY
CFR(s): 493.851(f)

(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 an off-site desk review of the Center for Medicaid and Medicare Services (CMS) CASPER 0155 report, the laboratory's proficiency testing (PT) records, and interview, the laboratory failed to attain a score of at least eighty percent (80%) of acceptable responses for Red Blood Cell (RBC) counts for two (2) consecutive Complete Blood Count (CBC) hematology testing events resulting in an unsuccessful PT performance as reviewed on the date of the inquiry May 6, 2025. Findings include:
1. Review of the CMS CASPER 0155 report revealed the following results:
Hematology 2024-3rd Event laboratory received an unsatisfactory score of 60% for analyte 0775 RBC; Hematology 2025-1st Event laboratory received an unsatisfactory score of 60% for analyte 0775 RBC. 2. Desk review of the laboratory's Medical Laboratory Evaluation a Service of the American Association of Bioanalysts (AAB-MLE) PT records on 5/6/25 revealed RBC scores of less than 80% for the following 2 consecutive hematology CBC events: 2024 AAB-MLE Event 3: RBC scored 60% (challenge sample 14 reported as 5.82 with acceptable range 5.11-5.76, challenge sample 15 reported as 2.55 with acceptable range 2.25-2.53); 2025 AAB-MLE Event 1: RBC scored 60% (challenge sample 1 reported as 2.44 with acceptable range 2.23-2.41, challenge sample 2 reported as 4.76 with acceptable range 5.12-5.55); resulting in an unsuccessful PT performance. 3. An interview with the technical consultant on 5/7/25 at 4:45 PM confirmed the above findings.

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 an off-site desk review of the Center for Medicaid and Medicare Services CASPER 0155 report, the laboratory's proficiency testing (PT) records and interview, the laboratory director (LD) failed to provide overall management and direction of the laboratory services. The LD failed to ensure the overall quality of the laboratory services provided. Refer to D6016

D6016

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1407(e)(4)(i)

(e)(4)(i) The proficiency testing samples are tested as required under Subpart H of this part;

This STANDARD is not met as evidenced by:

Based on an off-site desk review of the Center for Medicaid and Medicare Services (CMS) CASPER 0155 report, the laboratory's proficiency testing (PT) records, and interview, the laboratory director (LD) failed to ensure the overall quality of the laboratory services provided. The LD failed to ensure successful participation in a Health and Human Services (HHS) approved proficiency testing program. Refer to D2130 and D2131.