

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 44D0315624	<b>(X3) Date Survey Completed</b> 05/08/2018
<b>Name of Provider or Supplier</b> Prime Care Medical-Henderson	<b>Street Address, City, State</b> 426 White Avenue, Henderson, TN	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D2128</b>	<p>HEMATOLOGY CFR(s): 493.851(e)</p> <p>(1) For any unsatisfactory analyte or test performance or testing event for reasons other than a failure to participate, the laboratory must undertake appropriate training and employ the technical assistance necessary to correct problems associated with a proficiency testing failure. (2) For any unacceptable analyte or testing event score, remedial action must be taken and documented, and the documentation must be maintained by the laboratory for two years from the date of participation in the proficiency testing event.</p> <p>This STANDARD is not met as evidenced by: Based on review of the American Proficiency Institute (API) Hematology /Coagulation proficiency testing (PT) performance evaluation report for 2016 event 2 and 2017 event 1, the laboratory failed to evaluate unacceptable scores for the white blood cell count (WBC) and red blood cell count (RBC) analyte in 2016 and 2017. The findings include: 1. Review of the API PT performance evaluation report for 2016 event 2 revealed an unacceptable score for WBC for sample number HEM-08. Review of performance indicated by lab director's signature with no corrective action for unacceptable score. 2. Review of the API PT performance evaluation report for 2017 event 1 revealed an unacceptable score for RBC for sample number HEM-02. Review of performance indicated by lab director's signature with no corrective action for unacceptable score. 3. Interview with testing personnel number one on May 8, 2018 at 10:30 am confirmed the laboratory failed to evaluate unacceptable proficiency testing scores for the WBC analyte in 2016 and the RBC analyte in 2017.</p>
<b>D5209</b>	<p>PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235</p> <p>As specified in the personnel requirements in subpart M, the laboratory must establish</p>

and follow written policies and procedures to assess employee and, if applicable, consultant competency.

This STANDARD is not met as evidenced by:

Based on review of the laboratory's policy titled "Quality Assurance Program", and interview with testing personnel number one the laboratory failed to establish policies for competency assessment of testing personnel as specified in Subpart M in 2016, 2017, and 2018. The findings include: 1. Review of the laboratory's policy titled "Quality Assurance Program" revealed the following statement related to personnel competency "Personnel are evaluated annually or when new methodologies are incorporated." The laboratory's policy did not include the required 6 competency assessment elements or the frequency as specified in subpart M. The required elements include: Direct observation of routine patient test performance, including patient preparation, if applicable, specimen handling, processing and testing; Monitoring the recording and reporting of test results; Review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventive maintenance records; Direct observation of performance of instrument maintenance and function checks; Assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples; and Assessment of problem solving skills; Evaluating and documenting the performance of individuals responsible for moderate complexity testing at least semiannually during the first year the individual tests patient specimens. Laboratory director policy review noted for 2016, 2017, and 2018. 2. Interview with testing personnel number one on May 8, 2018 at 10:00 am confirmed the laboratory failed to have a policy for competency assessment of testing personnel that met the requirements as specified in Subpart M in 2016, 2017, and 2018.

**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:

The laboratory director failed to ensure the quality control program was maintained to assure quality of services offered (Refer to D6020).

**D6020**

**LABORATORY DIRECTOR RESPONSIBILITIES**  
CFR(s): 493.1407(e)(5)

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)(5) Ensure that the quality control program is established and maintained to assure the quality of laboratory services provided.

This STANDARD is not met as evidenced by:

Based on review of the Coulter 4C-ES quality control (QC) package insert, the printed

documents titled "Quality Control File" used for electronic management of quality control limits, in use dates, and laboratory director review of quality control, and interview with testing personnel number one, the laboratory director failed to ensure the quality control program was maintained in 2016, 2017, and 2018. The findings include: 1. Review of the Coulter 4C-ES QC package insert and the document titled "Quality Control File" printed from the electronic QC management system used for documenting QC limits, in use dates, and laboratory director review of quality control revealed the following: Lot Test Correct Range Range Used 069100 HGB 5.7 - 7.1 6.4 - 6.4 MCHC 31.6 - 38.4 35.0 - 35.0 RBC 2.11 - 2.61 2.36 - 2.36 Lab director signature on the control limit entry sheet dated 4-8-2016 079100 WBC 8.4 - 9.8 13.44 - 4.75 RDW 12.8 - 15.8 7.35 - 21.25 PLT 182 - 262 222 -222 Lab director signature on the control limit entry sheet dated 4-8-2016 089100-OK Documented review of lot #s 069100, 079100, 089100 by lab director and in use dates from 4-8-16 to 7-1-16. Lot Test Correct Range Range Used 069700 RBC 2.13 - 2.61 2.38-2.38 HGB 5.6 - 7.0 6.3 - 6.3 MCHC 31.8 - 38.7 35.2 - 35.2 Lab director signature on the control limit entry sheet dated 7-1-2016 079700 MO# .5 - 1.5 .7 - 1.7 GR# 3.2 - 5 3.1 - 4.9 WBC 8.3 - 9.7 13.44 - 4.75 RBC 3.9 - 4.4 3.96 - 4.46 HGB 12.1 - 13.0 11.3 - 13.1 HCT 31.8 - 37.8 32.1 - 38.1 MCV 79.4 - 88.4 78.9 - 87.9 MCH 25.9 - 32.5 25.7 - 32.3 RDW 13.1 - 16.1 7.35 - 21.25 PLT 173 - 253 222 - 222 MPV 9.5 - 13.5 9.2 - 13.2 LY% 38.6 - 48.6 37.5 - 47.5 MO% 7.3 - 15.3 9.4 - 17.4 GRAN% 39.1 - 51.1 38.1 - 50.1 089700 WBC 17.3 - 19.2 16.4 - 18.8 RBC 5.04 - 5.64 5.13 - 5.73 HGB 16.1 - 17.9 16.5 - 18.3 HCT 45.3 - 53.3 46.8 - 54.8 MCV 87.4 - 97.4 88.6 - 98.6 MCH 28.2 - 3.4 28.4 - 35.6 MCHC 30.9 - 38.1 30.7 - 37.9 RDW 12.2 - 16.2 11.2 - 15.2 PLT 315 - 435 318 - 438 MPV 9.7 - 13.7 9.6 - 13.6 LY% 42.9 - 52.9 42.8 - 52.8 MO% 9.9 - 19.9 11.5 - 21.5 GRAN% 32.2 - 42.2 30.7 - 40.7 LY# 7.4 - 10.4 6.9 - 9.9 MO# 1.6 - 4 1.7 - 4.10 GRAN# 5.4 - 8.2 4.9 - 7.7 Documented review of lot #s 069700, 079700, and 089700 by the laboratory director and in use dates from 7-1-16 to 9-27-16. Lot Test Correct Range Range Used 067900 RBC 2.10 - 2.6 2.35 - 2.35 HGB 5.5 - 6.9 6.2 - 6.2 MCHC 31.8 - 38.6 35.2 - 35.2 Lab director signature on the control limit entry sheet dated 9-27-16 077900 WBC 8.8 - 10.2 13.84 - 5.15 RDW 13.2 - 16.2 7.75 - 21.65 PLT 180 - 260 220 - 220 087900 OK Documented review of lot #s 067900, 077900, and 087900 by the laboratory director and in use dates from 9-27-16 to 1-3-17. Lot Test Correct Range Range Used 068600 RBC 2.15 - 2.65 2.40 - 2.40 HGB 5.9 - 7.3 6.6 - 6.6 MCHC 32.3 - 39.1 35.7 - 35.7 Lab director signature on the control limit entry sheet dated 1-3-17 078600 WBC 8.3 - 9.7 13.34 - 4.65 RDW 12.9 - 15.9 7.45 - 21.35 PLT 174 - 254 214 -214 088600 OK Documented review of lot #s 068600, 078600, and 088600 by the laboratory director and in use dates from 1-3-17 to 4-7-17. Lot Test Correct Range Range Used 069300 RBC 2.14 - 2.39 2.39 - 2.39 HGB 5.6 - 7 6.3 -6.3 MCHC 31.2 -38 34.6 - 34.6 079300 WBC 8.6 - 10.0 13.64 - 4.95 RDW 12.6 - 15.6 7.15 - 21.05 PLT 181 - 221 221 - 221 Lab director signature on the control limit entry sheet dated 4-7-17 089300 OK Documented review of lot #s 069300, 079300, ad 089300 by the laboratory director and in use dates from 4-7-17 to 07-17-17. Lot Test Correct Range Range Used 069900 RBC 2.08 - 2.58 2.33 - 2.33 HGB 5.6 - 7.0 6.3 - 6.3 MCHC 31.8 - 38.6 35.2 - 35.2 Lab director signature on the control limit entry sheet dated 7-17-17 079900 WBC 8.1 - 9.5 13.14 - 4.45 RDW 13.3 - 16.3 7.85 - 21.75 PLT 176 - 256 216 - 216 089900 OK Documented review of lot #s 069900, 079900, and 089900 by the laboratory director and in use dates from 7-17-17 to 10-5-17. Lot Test Correct Range Range Used 068100 RBC 2.25 - 2.75 2.5 - 2.5 HGB 6.1 - 7.3 6.6 - 6.6 MCHC 31.3 - 38.1 34.7 - 34.7 Lab director signature on the control limit entry sheet dated 10-5-17 078100 WBC 8.3 - 9.7 13.34 - 4.65 RDW 13.6 - 16.6 8.15 - 22.05 PLT 181 - 261 221 - 221 088100 OK Documented review of lot #s 068100 ,078100, 088100 by the laboratory director and in use dates from 10-5-17 to 1-10-18. Lot Test Correct Range Range Used 068800 RBC 2.13 - 2.63 2.38 - 2.38 HGB 5.7 - 7.1 6.4 -

6.4 MCHC 32.4 - 38.2 35.8 - 35.8 078800 WBC 8.1 - 9.5 13.14 - 4.45 RBC 3.85 - 4.35 4.10 - 4.10 RDW 13.2 - 15.2 7.75 - 21.65 PLT 187 - 267 227 - 227 088800 OK Documented review of lot #s 068800, 078800, and 088800 by the laboratory director and in use dates from 1-10-18 to 4-4-18. Lot Test Correct Range Range Used 069400 HGB 5.6 - 7.0 6.3 - 6.3 MCHC 32.2 - 39 35.6 - 35.6 RBC 2.08 - 2.58 2.33 - 2.33 Lab director signature on the control limit entry sheet dated 4-04-2018. 079400 WBC 8.3 - 9.7 13.34 - 4.65 RBC 3.89 - 4.39 4.14 - 4.14 RDW 13 - 16 7.55 - 21.45 PLT 186 - 266 226 - 226 089400-OK Lot numbers opened on 4-4-18 (Current lot) 2. Review of the quality control limits for the current lot numbers (069400, 079400, 089400) entered into the electronic quality control maintenance system during the survey revealed onsite correction of incorrect quality control limits for the current lot. 3. Interview with testing personnel number one on May 8, 2017 at 3:20 pm confirmed that the QC limits in use for the past two years have been incorrect for many analytes, testing personnel number one is responsible for entering the limits in the electronic QC system, did not know how to change the assigned standard deviation in the electronic QC system, there is documented review of QC and QC limits by the laboratory director and the laboratory director failed to ensure the quality control program was maintained to assure quality of services in 2016, 2017, and 2018.