

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  44D2059877	<b>(X3) Date Survey Completed</b>  06/04/2019
<b>Name of Provider or Supplier</b>  Family Care Walk-In Clinic, Inc	<b>Street Address, City, State</b>  400 Us Hwy 45w, Humboldt, 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>D5400</b>	<p><b>ANALYTIC SYSTEMS</b> CFR(s): 493.1250</p> <p>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.</p> <p>This CONDITION is not met as evidenced by: The laboratory failed to have a corrective action policy that specified the number of times complete blood count (CBC) quality control could be repeated (Refer to D5779), and failed to have an effective quality assessment process that corrected problems with CBC quality control errors (Refer to D5793).</p>
<b>D5779</b>	<p><b>CORRECTIVE ACTIONS</b> CFR(s): 493.1282(a)</p> <p>Corrective action policies and procedures must be available and followed as necessary to maintain the laboratory's operation for testing patient specimens in a manner that ensures accurate and reliable patient test results and reports.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory procedure manual, complete blood count (CBC) quality control (QC) records, patient test reports, and interview with the laboratory liaison, the laboratory procedure failed to include the number of times quality control could be repeated to obtain acceptable results before performing patient testing for CBC in 2017, 2018, and 2019. The findings include: 1) Review of the laboratory</p>

procedure titled "QUALITY ASSESSMENT PLAN" revealed no criteria for the number of times quality control (QC) could be repeated to obtain acceptable QC results. 2) Review of quality control records and patient test reports for the complete blood count instrument revealed the following: 8.28.2017: QC repeated multiple times (Low performed 3 times, Normal performed 5 times, High performed 2 times, and then patients were tested and reported (patient number one)). 01.26.2018: QC repeated multiple times (Low performed 7 times, Normal performed 4 times, High performed 8 times, and then patients were tested and reported (patient number six)). 05.02.2019: QC repeated multiple times (Low performed 6 times, Normal performed 3 times, High performed 2 times, and then patients were tested and reported (patient number seven)). 3) Interview with the laboratory liaison on June 4, 2019 at 1:00 pm confirmed the laboratory is repeatedly testing CBC quality control to get at least 2 levels within manufacturer's acceptable limits prior to patient testing. The laboratory procedure does not include the number of times QC can be repeated prior to performing patient testing in 2017, 2018, and 2019.

**D5793**

**ANALYTIC SYSTEMS QUALITY ASSESSMENT**  
CFR(s): 493.1289(b)(c)

(b) The analytic systems quality assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of analytic systems quality assessment reviews with appropriate staff. (c) The laboratory must document all analytic systems assessment activities.

This STANDARD is not met as evidenced by:

Based on review of the laboratory's complete blood count (CBC) quality control (QC) records, patient test reports, quality assessment records, proficiency testing records and interview with the laboratory liaison the laboratory quality assessment process was ineffective when it failed to correct multiple, consistent problems with quality control for the complete blood count (CBC) instrument in 2017, 2018 and 2019. The findings include: 1) Review of the laboratory's CBC quality control records, patient test reports and quality assessment records for 2017, 2018 and 2019 revealed multiple and recurring instances where CBC quality control was repeated multiple times before obtaining acceptable quality control. Imprecision was noted for the white blood cell (WBC) and platelet analytes. The issues noted have been persistent and ongoing since 2017. Quality assessment and corrective actions have not been effective in correcting the problem. Examples of repeated CBC QC with patient testing performed: 8.28.2017: QC continually repeated (Low performed 3 times, Normal performed 5 times, High performed 2 times, and then patients were tested and reported (patient number one). 01.26.2018: QC continually repeated (Low performed 7 times, Normal performed 4 times, High performed 8 times, and then patients were tested and reported (patient number six). 05.02.2019: QC continually repeated (Low performed 6 times, Normal performed 3 times, High performed 2 times, and then patients were tested and reported (patient number seven). Quality control reviews: Lot number EX0717 in use 7.06.2017 to 10.04.2017: Multiple dates where QC was performed repeatedly before obtaining acceptable results: 08.26.2017, 08.28.2017, 09.09.2017, 09.13.2017, 9.23.2017, 9.24.2017, 9.26.2017. Dates where imprecision was noted (all units are in th/uL): 09.13.2017 Low level QC for WBC: run one = 2.1, run two = 2.1, run three = 107.3, run four = 2.3, run five = 2.1 Quality assessment reviews for this time period revealed the following: 7.24.2017 Noted issues were present with shift in platelets, hematocrit QC being out of range, background counts out of range with

corrective action of "aggressive clean procedure performed on 7.12.17." "Lab is performing well at this time" was noted on the overall quality assessment. 09.22.2017 Multiple issues were noted on the quality assessment document including problems with background count and quality control. Corrective action included aggressive cleaning performed on 9.7.17. There was no effective investigation into the cause of the QC failures or documentation of effective corrective action to correct the problems with the CBC quality control including the number of times the CBC quality control had to be performed to obtain acceptable results. Lot number EX0118 in use 01.06.2018 to 04.03.2018: Multiple dates where QC was performed repeatedly before obtaining acceptable results: 01.06.2018, 01.11.2018, 01.21.2018, 01.26.2018, 02.09.2018, 02.16.2018, 02.19.2018, 03.01.2018, 03.02.2018, 03.10.2018, 03.17.2018, 03.18.2018, 03.21.2018, 03.23.2018, 04.03.2018. Quality control had been reviewed by the technical consultant. Dates where imprecision was noted (all units are in th/uL): 02.16.2018 Low level QC for WBC: run one = 64.0, run two = 66.4, run three = 2.2 02.16.2018 Low level QC for PLT: run one = 124, run two = 117, run three = 70 Quality assessment reviews for this time period revealed the following: 01.26.2018 stated "Needs improvement; problems with controls for CBC analyzer have caused unnecessary problems." No corrective actions were performed. 03.27.2018 stated "Needs improvement when performing QC." Training done with employees for ensuring 2 levels of controls were in before patient testing. There was no effective investigation into the cause of the QC failures or documentation of effective corrective action to correct the problems with the quality control including the number of times the quality control had to be performed to obtain acceptable results. Lot EX0419 dates in use 03.28.2019 to current date: Multiple dates where QC was performed repeatedly before obtaining acceptable results: 04.01.2019, 04.11.2019, 05.02.2019, 05.12.2019, 04.16.2019, 04.24.2019, 05.01.2019, 05.11.2019. Dates where imprecision was noted (all units are in th/uL): 04.11.2019 Low level QC for WBC run one = 81.7, run two = 2.4. 05.02.2019 Low level QC for WBC run one = 2.3, run 2 =2.1, run 3 = 134.5, run 4=3.2. 05.02.2019 Low level QC for PLT run one = 70, run 2 = +++++, run 3 = 127, run 4=66, run 5=73, run 6=62. Quality assessment review for this time period revealed the following: 05.23.2019- "Lot # reviewed EX0419" "QC is acceptable March - May 2019. Few days one level was out but alternate QC was acceptable." "Lab is performing well." Corrective Actions Taken= None. There was no documented investigation into the cause of the QC failures or imprecision in the WBC and platelet counts. 2) Review of the laboratory's bi-monthly quality assessment records beginning 05.22.2017 through 05.23.2019 revealed consistent problems documented for the past two years including failed proficiency testing. There was occasional documentation of efforts to correct problems with QC, including following manufacturer's recommendations for extended maintenance, recalibration, etc. The corrective action noted for the imprecision for the WBC and platelets was that it was repeated or the alternate QC was acceptable. There was no investigation into the cause of the imprecision. The quality assessments for the past two years do not show effective corrective action for the cause of the multiple failures in QC and imprecision for the WBC and PLT counts. Most corrective action includes the QC was repeated, alternate QC was acceptable, or aggressive cleaning performed. 3) Review of the laboratory's CBC proficiency testing scores for 2017, 2018 and 2019 revealed failing scores for the RBC analyte for 3 of the last 7 survey survey events (2017 event 1=0%, 2017 event 3=0%, 2019 event one =20%). 4) Interview with the laboratory liaison on June 4, 2019 at 2:00 pm confirmed the laboratory's quality assessment was ineffective when it failed to correct problems with CBC quality control in 2017, 2018, and 2019. The problems are persistent and ongoing for the last two years, corrective actions applied have been recalibration, additional bleaching, and aggressive clean procedures but the problems have not been

corrected. The quality assessment performed was not effective.