

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 44D0313244	<b>(X3) Date Survey Completed</b> 07/23/2019
<b>Name of Provider or Supplier</b> Brownsville Family Medicine	<b>Street Address, City, State</b> 2290 N Washington Ave, Brownsville, 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>D5405</b>	<p>PROCEDURE MANUAL CFR(s): 493.1251(c)</p> <p>Manufacturer's test system instructions or operator manuals may be used, when applicable, to meet the requirements of paragraphs (b)(1) through (b)(12) of this section. Any of the items under paragraphs (b)(1) through (b)(12) of this section not provided by the manufacturer must be provided by the laboratory.</p> <p>This STANDARD is not met as evidenced by: Based on observation of the laboratory, review of the available procedure manuals and interview with testing personnel number one, the laboratory failed to have the Sysmex XP-300 complete blood count (CBC) instrument operator's manual available for testing personnel, in 2017, 2018 and 2019. The findings include: 1) Observation of the laboratory on July 23, 2019, at 2:30 p.m. revealed the Sysmex XP-300 CBC instrument, serial number B3505, in use for CBC patient testing. 2) Review of all available procedure manuals revealed the Sysmex XP-300 CBC instrument operator's manual was not available in written form or disk. 3) Interview on July 23, 2019, at 3:30 p.m. with testing personnel number one confirmed the Sysmex XP-300 CBC instrument was installed November 9, 2017 with no operator's manual available in the laboratory.</p>
<b>D6033</b>	<p>TECHNICAL CONSULTANT-MODERATE COMPEXITY CFR(s): 493.1409</p> <p>The laboratory must have a technical consultant who meets the qualification requirements of 493.1411 of this subpart and provides technical oversight in accordance with 493.1413 of this subpart.</p> <p>This CONDITION is not met as evidenced by:</p>

The technical consultant failed to provide documentation of either training or experience in the specialties of Hematology and Parasitology (Refer to D6034).

**D6034**

**TECHNICAL CONSULTANT QUALIFICATIONS**

CFR(s): 493.1411

The laboratory must employ one or more individuals who are qualified by education and either training or experience to provide technical consultation for each of the specialties and subspecialties of service in which the laboratory performs moderate complexity tests or procedures. The director of a laboratory performing moderate complexity testing may function as the technical consultant provided he or she meets the qualifications specified in this section.

This STANDARD is not met as evidenced by:

Based on observation of the laboratory, review of the Laboratory Personnel Report Centers for Medicare and Medicaid (form CMS-209), personnel records and interview with testing personnel number one, the technical consultant failed to provide documentation of either training or experience in the specialties of Hematology and Parasitology. The findings include: 1) Observation on July 23, 2019, at 2:30 p.m. of the laboratory revealed a microscope and a Sysmex XP-300 complete blood count (CBC) instrument in use for wet prep and CBC patient testing. 2) Review of the CMS-209 Laboratory Personnel Report revealed no technical consultant listed. 3) Review of the available personnel records revealed no documentation of either training or experience for anyone, in the specialties of Hematology and Parasitology. 4) Interview on July 23, 2019 at 3:30 p.m. with testing personnel number one confirmed the CBC and wet prep are performed for patient testing. The technical consultant training and experience for Hematology and Parasitology were not available for review. The previous technical consultant retired December 2018.