Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	44D0953252	01/09/2020
Name of Provider or Supplier	**Street Address, City, State**	
Brownsville Medical Clinic Pa	3363 North Highland Ave, Jackson, TN	

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	493.51 Notification requirements for laboratories issued a certificate of compliance Laboratories issued a certificate of compliance must meet the following conditions: (a) Notify HHS or its designee within 30 days of any change in-- (1) Ownership; (2) Name; (3) Location; (4) Director; or (5) Technical supervisor (laboratories performing high complexity only). (b) Notify HHS no later than 6 months after performing any test or examination within a specialty or subspecialty area that is not included on the laboratory ' s certificate of compliance, so that compliance with requirements can be determined. (c) Notify HHS no later than 6 months after any deletions or changes in test methodologies for any test or examination included in a specialty or subspecialty, or both, for which the laboratory has been issued a certificate of compliance. This requirement is not met as evidenced by: Based on observation of the laboratory, review of laboratory records, the Aspen 116 database, and interview with the lead testing personnel, the laboratory failed to notify the state agency of change in specialties within six months of the change in 2019. The findings include: 1) Observation of the laboratory on January 9, 2020 at 8:00 a.m. revealed the Cell-Dyn 1700 Complete Blood Count (CBC) instrument on the counter. The instrument was not being used for patient testing for CBC. 2) Review of the laboratory's corrective action log for the Cell-Dyn 1700 revealed the instrument was removed from use on January 3, 2019. 3) Review of the Aspen 116 database revealed no communication from the laboratory for change in specialties. 4) Interview on January 9, 2020 at 11:45 a.m. with the lead testing personnel confirmed the laboratory failed to notify the state agency of the change in specialties in 2019.
D3031	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3) Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years.

	This STANDARD is not met as evidenced by: Based on review of final patient test reports for complete blood count (CBC), records for the complete blood count (CBC) instrument, and interview with the lead testing personnel, the laboratory failed to retain all analytic test records for two years. 1) Review of patient numbers one, two and three test reports for CBC revealed patient testing for complete blood count performed on November 6, 2018, June 22, 2018, and January 3, 2019, respectively. 2) Review of CBC instrument records revealed no initial instrument printouts were available for patient numbers one and two; no quality control records were available for November 6, 2018, June 22, 2018 and January 3, 2019. 3) Interview with the lead testing personnel on January 9, 2020 at 11:45 a.m. confirmed the laboratory failed to retain all analytic test records for CBC for at least two years in 2020.
D5200	GENERAL LABORATORY SYSTEMS CFR(s): 493.1230 Each laboratory that performs nonwaived testing must meet the applicable general laboratory systems requirements in 493.1231 through 493.1236, 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 general laboratory systems and correct identified problems specified in 493.1239 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: The laboratory failed to follow testing personnel competency policy (Refer to D5209), failed to verify the accuracy of urine microscopy (Refer to D5217), failed to follow the quality assessment plan (Refer to D5291); and failed to have an effective quality quality assessment process (Refer to D5793).
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish 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 competency policy, the Centers for Medicare and Medicaid Services Laboratory Personnel Report (Form CMS-209), testing personnel records, and interview with the lead testing personnel, the laboratory failed to follow the policy for competency assessment in 2018 and 2019. 1) Review of the laboratory's testing personnel competency assessment policy revealed that all staff will be trained for any tests they perform and supervised until competent; Competency will be assessed at 6 months, and then at a year for new hires; annually for established employees. 2) Review of the Centers for Medicare and Medicaid Services Laboratory Personnel Report (CMS-209) revealed the name of testing personnel number two, new since the last survey date. 3) Review of testing personnel records revealed no initial training, 6 month competency assessment, or yearly competency assessment for testing personnel number two; no annual competency assessment for testing personnel one. 4) Interview with the lead testing personnel on January 9, 2020 at 11:45 a.m. confirmed the laboratory's testing personnel competency policy was not followed in

	2018 and 2019. Testing personnel number two began patient testing for urine microscopy in 2018.
D5217	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1) At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part. This STANDARD is not met as evidenced by: Based on review of the laboratory's proficiency testing records and interview with the lead testing personnel, the laboratory failed to verify the accuracy of urine microscopy twice a year in 2019. The findings include: 1) Review of the laboratory's proficiency testing records revealed the laboratory did not submit proficiency testing results for 2019 events one and three for urine microscopy. No other records/methods were present for verification of accuracy for urine microscopy in 2019. 2) Interview on January 9, 2020 at 11:45 a.m. confirmed the laboratory uses proficiency testing to verify the accuracy of urine microscopy procedures and failed to verify the accuracy of urine microscopy procedures twice a year in 2019.
D5291	GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and, when indicated, correct problems identified in the general laboratory systems requirements specified at 493.1231 through 493.1236. This STANDARD is not met as evidenced by: Based on review of the laboratory's quality assurance plan, review of laboratory records, and interview with the lead testing personnel, the laboratory failed to follow the quality assessment plan in 2019. The findings include: 1) Review of the laboratory's quality assurance plan revealed that 10 records would be reviewed for errors each year. 2) Review of laboratory records revealed no patient records review was performed for urine microscopy in 2019. 3) Interview with the lead testing personnel on January 9, 2020 at 11:45 a.m. confirmed the laboratory failed to follow the quality assessment plan for patient test management in 2019.
D5293	GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(b)(c) (b) The general laboratory 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 general laboratory systems quality assessment reviews with appropriate staff. (c) The laboratory must document all general laboratory systems quality assessment activities. This STANDARD is not met as evidenced by: Based on review of the laboratory's proficiency testing records, and interview with the lead testing personnel, the laboratory's quality assessment was ineffective when it

	failed to correct problems with proficiency testing in 2019. The findings include: 1) Review of the laboratory's proficiency testing records revealed results were not submitted for 2019 events one and three for urine microscopy. 2019 event two was not reviewed by the laboratory director. No corrective action was documented for the failure to submit proficiency testing results for urine microscopy, 2019 events one and three, or failure to review proficiency testing for 2019 event two. 2) Interview with the lead testing personnel on January 9, 2020 confirmed the laboratory's quality assessment process was ineffective when it failed to correct problems with proficiency testing in 2019.