Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D1004954	01/08/2018
Name of Provider or Supplier	**Street Address, City, State**	
Bhs Physicians Network	1626 E Common Street, New Braunfels, TX	

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	The laboratory was found to be out of compliance based on the following CONDITION LEVEL DEFICIENCIES: D2000 - 42 C.F.R. 493.1210 Condition: Routine Chemistry D6000 - 42 C.F.R. 493.1405 Condition: Laboratory Director; moderate complexity D6033 - 42 C.F.R. 493.1409 Condition: Technical Consultant; moderate complexity Noted deficiencies and plans of correction were discussed with the laboratory representative at the exit conference. The facility representative was given an opportunity to provide evidence of compliance with noted deficiencies and no such evidence was provided prior to survey exit. Note: The CMS-2567 (Statement of Deficiencies) is an official, legal document. All information must remain unchanged except for entering the plan of correction, correction dates, and the signature space. Any discrepancy in the original deficiency citation(s) will be reported to the Dallas Regional Office (RO) for referral to the Office of the Inspector General (OIG) for possible fraud. If information is inadvertently changed by the provider /supplier, the State Survey Agency (SA) should be notified immediately.
D1001	CERTIFICATE OF WAIVER TESTS CFR(s): 493.15(e) Laboratories eligible for a certificate of waiver must-- (1) Follow manufacturers' instructions for performing the test; and (2) Meet the requirements in subpart B, Certificate of Waiver, of this part. This STANDARD is not met as evidenced by: Based on review of manufacturer's instructions for the Abbott i-STAT analyzer, review of the laboratory's inventory records, and staff interview, it was revealed the laboratory failed to have documentation of following the manufacturer's requirement to document the temperature of cartridges shipped to the laboratory to ensure they maintained the proper temperature during shipment. The findings were: 1. A review of the manufacturer's instructions for the Abbott i-STAT analyzer (Revision date 31-Jan-12) under the section titled "Periodic Procedure for Cartridges" revealed: "Check

	Temperature Monitor i-STAT cartridges are shipped refrigerated with a four-window indicator to monitor temperature during transit. Action: - Fill out the record of receipt and forward material to refrigerator - If all windows are white or if only the A and B windows are blue or the 1 or 2 windows are red, then transit temperatures were satisfactory and the cartridges can be used. Remedial Action: If the C or D windows or the 3 and 4 windows are red: - Quarantine the suspect cartons - Notify the i-STAT System Coordinator immediately - DO NOT USE cartridges from the suspected cartons - Records the out-of-control event in the i-STAT QC Log 2. A review of the laboratory's inventory logs from January 2017 to 2018 revealed the laboratory received 38 shipments of CHEM 8+ cartridges. Cartridges were received on the following days: Date # of boxes in shipment 01/06/2017 4 01/16/2017 5 01/20/2017 4 02/03/2017 3 02/13/2017 5 02/20/2017 4 03/17/2017 2 03/24/2017 4 03/31/2017 3 04 /07/2017 3 04/14/2017 3 04/24/2017 4 05/05/2017 4 05/22/2017 4 06/05/2017 3 06/09 /2017 3 06/16/2017 3 06/23/2017 2 06/30/2017 4 07/14/2017 3 07/21/2017 2 07/28 /2017 3 08/18/2017 3 08/31/2017 2 09/21/2017 4 09/28/2017 3 10/06/2017 1 10/06 /2017 3 10/12/2017 3 10/19/2017 3 10/26/2017 3 10/26/2017 1 11/02/2017 3 11/09 /2017 2 11/14/2017 3 12/07/2017 3 12/21/2017 3 01/04/2017 3 3. The laboratory was asked to provide documentation of the record of receipt for each of the identified shipments including documentation of the temperature at receipt to ensure cartridges maintained the required temperature during shipment. No documentation was provided. 4. An interview with testing personnel number 2 (as listed on Form CMS 209) on 01/08/2018 at 1045 hours in the laboratory revealed the laboratory did not monitor the temperature of the cartridges upon arrival and did not retain the record of receipt for each shipment. This confirmed the findings.
D2007	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) The samples must be examined or tested with the laboratory's regular patient workload by personnel who routinely perform the testing in the laboratory, using the laboratory's routine methods This STANDARD is not met as evidenced by: Based on review of the laboratory's submitted Form CMS 209, review of the laboratory's American Proficiency Institute's proficiency testing records from 2016 and 2017, and staff interview, it was revealed the laboratory failed to have documentation of rotating proficiency testing among testing personnel who routinely performed testing. The findings were: 1. A review of the laboratory's submitted Form CMS 209 (signed by the laboratory director on 01/06/2018) revealed the laboratory identified 9 testing personnel. 2. A review of the laboratory's American Proficiency Institute's proficiency testing records from 2016 (Chemistry Group 1 events 1, 2, and 3) and 2017 (Chemistry Core events 1, 2, and 3) revealed the following testing personnel (as listed on Form CMS 209) performed testing of the proficiency testing samples: 2016 event 1 Testing personnel number 1 Testing personnel number 2 2016 event 2 Testing personnel number 2 2016 event 3 Testing personnel number 2 2017 event 1 Testing personnel number 2 2017 event 2 Testing personnel number 2 2017 event 3 Testing personnel number 2 There was no documentation of testing personnel 3, testing personnel number 4, testing personnel number 5, testing personnel number 6, testing personnel number 7, testing personnel number 8 or testing personnel number 9 participating in proficiency testing. 3. The laboratory was asked to provide documentation of the identified testing personnel participating in proficiency testing. No documentation was provided. 4. An interview with testing personnel number 2 (as

	listed on Form CMS 209) on 01/08/2018 at 1030 hours in the break room revealed only she performed testing of the proficiency samples. She stated other personnel who routinely tested patient samples did not participate in proficiency testing. This confirmed the findings. NOTE: THIS IS A REPEAT DEFIENCY FROM THE SURVEY CONDUCTED ON 12/02/2015
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 the lack of instrument printouts for patient test results, and staff interview, it was revealed the laboratory failed to have documentation of retaining instrument printouts for cardiac testing performed on the Biosite Triage Meter Pro analyzer. The findings were: 1. The laboratory was asked to provide documentation of instrument printouts for cardiac tests performed on the Biosite Triage Meter Pro analyzer. No documentation was provided. 2. The laboratory reported performing 930 cardiac tests annually. 3. An interview with testing personnel number 2 revealed the laboratory would remove the printout from the analyzer, manually document the results on a patient log and then enter the results into the patient's electronic medical record. The original printout was then placed in a box for shredding. When asked how the laboratory would identify if a clerical error had occurred without the original instrument printout to compare the results to, she stated she did not know. She then agreed the laboratory should retain the instrument printouts. This confirmed the findings.
D5016	ROUTINE CHEMISTRY CFR(s): 493.1210 If the laboratory provides services in the subspecialty of Routine Chemistry, the laboratory must meet the requirements specified in 493.1230 through 493.1256, 493. 1267, and 493.1281 through 493.1299. This CONDITION is not met as evidenced by: Based on review of the laboratory's records and staff interview, it was revealed the laboratory failed to meet the requirements for the specialty of chemistry. The findings were: 1. The laboratory failed to have documentation of a competency assessment being performed on 1 of 2 technical consultants (refer to D5209). 2. The laboratory failed to have documentation of the review of proficiency testing results (refer to D5211) This is a repeat deficiency from the survey conducted on 12/02/2015 3. The laboratory failed to have a quality assessment plan which could monitor, detect and correct problems in general laboratory systems (refer to D5291). 4. The laboratory failed to have documentation of monitoring quality control values over time (refer to D5441). This is a repeat deficiency from the survey conducted on 12/02/2015 5. The laboratory failed to have documentation of performing quality control testing each day of patient testing (refer to D5447). 6. The laboratory failed to have a quality assessment plan which could monitor, detect and correct problems in analytic systems (refer to D5791).

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 submitted Form CMS 209, review of the laboratory's personnel records, and staff interview, it was revealed the laboratory failed to have documentation of a competency assessment being performed on 1 of 2 technical consultants. The findings were: 1. A review of the laboratory's submitted Form CMS 209 (signed by the laboratory director on 01/06/2018) revealed the laboratory identified two technical consultants. Technical consultant number 1 was also the laboratory director so a competency assessment was not required. 2. A review of the laboratory's personnel records revealed the laboratory failed to have documentation of a competency assessment being performed on technical consultant number 2. 3. The laboratory was asked to provide documentation of a competency assessment being performed on technical consultant number 2 to assess how well she was performing her duties as the technical consultant. No documentation was provided. 4. An interview with testing personnel number 2 (as listed on Form CMS 209) on 01/08/2018 at 1018 hours in the break room revealed the person identified as technical consultant number 2 was responsible for performing competency assessments of testing personnel. She stated a competency assessment for technical consultant number 2 had not been performed. This confirmed the findings.
D5211	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(a) The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part. This STANDARD is not met as evidenced by: Based review of the laboratory's American Proficiency Institute's proficiency testing results from 2016 and 2017, and staff interview, it was revealed the laboratory failed to have documentation of the review of 4 of 6 events. The findings were: 1. A review of the laboratory's American Proficiency Institute's proficiency testing results from 2016 (Chemistry Group 1 events 1, 2, and 3) and 2017 (Chemistry Core events 1, 2, and 3) revealed the laboratory failed to have documentation of the review of results for 4 of 6 events. The events missing documentation of the review of the results were: 2016 event 1 2016 event 2 2016 event 3 2017 event 3 2. The laboratory was asked to provide documentation of the review of the results. No documentation was provided. 3. An interview with testing personnel number 2 (as listed on Form CMS 209) on 01 /08/2018 at 1030 hours in the break room- after her review of the records- confirmed the findings. NOTE: THIS IS A REPEAT DEFICIENCY FROM THE SURVEY CONDUCTED 12/02/2015
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 records, and staff interview, it was revealed the laboratory failed to have documentation of a quality assessment plan to monitor, assess, and correct issues in general laboratory systems. The findings were: 1. The laboratory failed to have a quality assessment plan which identified and corrected that a competency assessment was not performed on 1 of 2 technical supervisors (refer to D5209). 2. The laboratory failed to have a quality assessment plan which identified and corrected that the review of proficiency testing results were documented (refer to D5211).
D5441	CONTROL PROCEDURES CFR(s): 493.1256(a)(b)(c)(g) (a) For each test system, the laboratory is responsible for having control procedures that monitor the accuracy and precision of the complete analytic process. (b) The laboratory must establish the number, type, and frequency of testing control materials using, if applicable, the performance specifications verified or established by the laboratory as specified in 493.1253(b)(3). (c) The control procedures must-- (c)(1) Detect immediate errors that occur due to test system failure, adverse environmental conditions, and operator performance. (c)(2) Monitor over time the accuracy and precision of test performance that may be influenced by changes in test system performance and environmental conditions, and variance in operator performance. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of the laboratory's quality control records from 2016 and 2017, and staff interview, it was revealed the laboratory failed to have documentation of monitoring quality control values for CK-MB, Troponin, and Myoglobin over time to detect shifts and trends. The findings were: 1. A review of the laboratory's quality control records from January 2016 to December 2017 revealed the laboratory failed to have documentation on monitoring the results of its quality control testing over time for the analytes of CK-MB, Troponin, and Myoglobin. 2. The laboratory was asked to provide documentation of having a mechanism in place to monitor the control values to identify shifts and trends. No documentation was provided. 3. The laboratory reported performing 930 cardiac tests annually. 4. An interview with testing personnel number 2 (as listed on Form CMS 209) on 01/08/2018 at 1100 hours in the break room revealed the laboratory only assessed the quality control values by ensuring they were within the manufacturer's acceptable ranges. She stated the laboratory did not monitor the control values to identify shifts and trends. This confirmed the findings. Key CK-MB: creatine kinase - muscle/brain
D5447	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(i)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- At least once a day patient specimens are assayed or examined perform the following

	for-- Each quantitative procedure, include two control materials of different concentrations; (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of the laboratory's quality control records from 2017, review of patient test records from 2017, and staff interview, it was revealed the laboratory failed to have documentation of performing quality control testing each day of patient testing for CK-MB, troponin, and myoglobin testing. The findings were: 1. A review of the laboratory's quality control records from 2017 revealed the laboratory performed quality control testing for CK-MB, troponin, and myoglobin testing every 30 days. 2. The laboratory was asked to provide documentation of developing a IQCP (individualized quality control plan) to support the modification of the regulations to allow quality control testing every 30 days. No documentation was provided. 3. A sampling of patient test records from 2017 identified the following patients whose samples were tested on days without documentation of quality control testing being performed: Date Sample Identification 01/05 6605 1276 8617 01/06 4805 6498 9220 01/09 6264 01/11 7266 01/12 5908 1869 01/13 2397 01/16 9256 01/18 6950 01/20 4283 01/24 2432 01/24 2470 01/25 5014 01/25 0694 01/25 8004 04/03 1060 8790 04 /04 7015 5098 04/05 2065 6274 8903 04/06 2373 5091 04/10 4343 5123 04/11 1182 1256 04/18 3854 3331 04/20 5367 1698 1109 04/21 4467 04/25 5720 1539 04/26 0507 04/27 9020 9997 07/05 0825 07/06 9950 4656 07/07 9856 07/10 5946 07/11 6726 07/12 6700 1042 3902 07/13 8775 07/14 7084 07/15 2308 07/18 3162 07/20 1147 07/24 5902 7155 0789 07/26 8242 1968 07/31 8414 10/03 0947 10/04 5238 10 /05 7712 5615 10/06 1661 0453 7069 9378 6248 10/10 3446 1832 10/11 2744 0686 10 /12 0365 10/16 3637 10/17 4726 10/18 2989 0000 10/19 6603 7992 9256 1231 10/25 4064 7951 10/27 2195 5553 10/30 2659 9458 4. An interview with testing personnel number 2 (as listed on Form CMS 209) on 01/08/2018 at 1045 hours in the break room revealed the laboratory did not perform a IQCP to support its testing of quality control material every 30 days. She stated she was unaware of the requirement to test quality control each day of patient testing. This confirmed the findings.
D5791	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c) (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 analytic systems specified in 493.1251 through 493.1283. (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 quality control records, and staff interview, it was revealed the laboratory failed to have a quality assessment plan which could monitor, detect and correct problems in analytic systems. The findings were: 1. The laboratory failed to have a quality assessment plan which detected and corrected that the laboratory failed to monitor quality control results over time to identify shifts and trends (refer to D5441). 2. The laboratory failed to have a quality assessment plan which detected and corrected that the laboratory failed to have documentation of performing quality control testing each day of testing for cardiac testing performed on the Biosite Triage Meter Pro analyzers (refer to D5447).
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 review of the laboratory's records, and staff interview, it was revealed the laboratory director failed to provide overall management and direction for the laboratory. The findings were: 1. The laboratory director failed to ensure the review of proficiency testing results were documented (refer to D6018). 2. The laboratory director failed to ensure a quality control plan was established and followed (refer to D6020). 3. The laboratory director failed to ensure a quality assessment plan was established and followed (refer to D6021).
D6018	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iii) 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)(4)(iii) Ensure that all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action; This STANDARD is not met as evidenced by: Based on review of the laboratory's American Proficiency Institute's proficiency testing results from 2016 and 2017, and staff interview, it was revealed the laboratory director failed to ensure proficiency testing results were reviewed (refer to D5211).
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 laboratory's quality control records from 2016 and 2017, and staff interview it was revealed the laboratory director failed to ensure and quality control plan was established and followed. The findings were: 1. The laboratory director failed to ensure quality control results were monitored over time to detect shifts and trends (refer to D5441). 2. The laboratory director failed to ensure quality control testing was performed each day of patient testing for cardiac testing performed on the Biosite Triage Meter Pro analyzers (refer to D5447).

D6021	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 quality assessment programs are established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based on review of the laboratory's records, and staff interview, it was revealed the laboratory director failed to ensure a quality assessment plan was established and followed to detect and correct errors. The findings were: 1. The laboratory director failed to ensure a quality assessment plan was established and followed to detect problems with general laboratory systems (refer to D5291). 2. The laboratory director failed to ensure and quality assessment plan was established and followed to detect problems with analytic systems (refer to D5791).
D6033	TECHNICAL CONSULTANT-MODERATE COMPEXITY CFR(s): 493.1409 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. This CONDITION is not met as evidenced by: Based on review of the laboratory's personnel records, and staff interview, it was revealed the technical consultant failed to provide technical oversight for the laboratory (refer to D6046).
D6046	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8) (b) The technical consultant is responsible for-- (b)(8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently. This STANDARD is not met as evidenced by: Based on review of the laboratory's personnel records, and staff interview, it was revealed the technical consultant failed to perform competency assessments on 4 of 7 testing personnel who required them in 2016 and 2017. The findings were: 1. CLIA regulations require competency assessment for testing personnel be performed by evaluating the following criteria: - direct observation of the testing procedure - monitoring of the recording and reporting of results - review of QC - direct observation of maintenance and function checks - assessment of test performance through previously analyzed specimen, blind samples, proficiency testing, etc. - assessment of problem solving skills. 2. A review of the laboratory's personnel revealed the technical consultant who performed competency assessments only documented the assessment of problem solving skills (a quiz) in 2016 and 2017 for

	the following testing personnel (as listed on Form CMS 209): Testing personnel number 2 Testing personnel number 3 Testing personnel number 5 Testing personnel number 6 3. The laboratory was asked to provide documentation of the technical consultant including the other required criteria as part of the competency assessments. No documentation of provided. 4. An interview with testing personnel number 2 on 01 /08/2018 at 1000 hours in the break room - after her review of the records, confirmed the findings. NOTE: THIS IS A REPEAT DEFICIENCY FROM THE SURVEY CONDUCTED ON 12/02/2015.