Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number** 49D0232228	**(X3) Date Survey Completed** 02/14/2019
Name of Provider or Supplier Dickenson Community Hospital, Inc	**Street Address, City, State** 312 Hospital Drive, Clintwood, VA	

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	An announced CLIA Validation survey was conducted at the Dickenson Community Hospital on February 12-14, 2019 by the Virginia Department of Health's Office of Licensure and Certification. The laboratory was surveyed under 42 CFR part 493 CLIA Requirements. Specific deficiencies cited are as follows:
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: A. Based on the review of policy and procedures (P&P), and an interview with the technical supervisor, the lab failed to retain the documentation of establishing the mean and standard deviation (SD) for the new lot number (L3186) of BioRad LiquiChek Unassayed Chemistry Controls at the dates of survey on February 12-14, 2019. Dates of record review included January 1, 2017 and up to February 14, 2019. Findings include: 1. The lab uses the BioRad LiquiChek Unassayed Chemistry Controls to perform daily quality control procedures on the Siemens Dimension EXL chemistry analyzer. Review of the P&P "Lab General Policy and Procedure", " 4.0 Quality Control", signed approved by the lab director on 10/04/18, revealed the following statements: "A minimum of 20 test values should be used to establish a Mean (x) and Standard Deviation (SD). The SD values determine quality control limits. Ideally 20 measurements should be ran over a 20 day period. The average and SD must be established each time there is a lot number change in QC materials in order to validate new lot." 2. The laboratory changed lot numbers from L3180 (exp date 06/30/18) to L31860 (06/30/19) during the month of June 2018. The inspector requested to review the documentation of the initial verification of the new lot number according to the above-specified policy. The documentation was not available for

	review. 3. The technical supervisor confirmed in an interview at approximately 1:00 PM on February 13, 2019 that the requested documentation was not available. B. Based on the review of policy and procedures (P&P), available quality control (QC) records, manufacturer package inserts (PI), instrument test data, and an interview with the technical supervisor, the lab failed to retain the documentation of the daily QC procedures for six (6) of 9 Beckman Coulter "6C Cell Control" lot numbers used from January 1, 2018 through August 19, 2018. Findings include: 1. Review of the P&P "Quality Control Procedures and Review", "Hematology Quality Control" revealed the following statements: "3.0 Quality Control- When control results are reviewed, the results are checked against the +2 SD control ranges where applicable. Anytime a result correction is entered, a comment must be entered stating what the problem was and how it was corrected. 6.0 Notes- Controls are reviewed and acceptable prior to reporting patient results. QC statistics are viewed monthly by Lab Service Manager and pathologist." An interview with the technical supervisor at approximately 1:00 PM on February 14, 2019 revealed that the lab does not print out the daily QC records or end of the month statistics for review. She/he stated the hematology QC records were reviewed within the DxH 600 hematology analyzer's hard drive. Comments regarding QC corrective actions are typed as a comment on the daily run. 3. Review of the Beckman Coulter Intralaboratory Quality Assurance Program (IQAP) and PI's revealed the lab utilized the following lot numbers from January 1, 2018 and up to August 19, 2018: 123171970, 133181970, 143191970- in use 1/11/18, 123171990, 133181990, 143191990- in use 2/11/18, 123172040, 133182040, 143192040- in use 3 /6/18, 123172070, 133182070, 143192070- in use 3/31/18, 123172110, 133182110, 142192110- in use 5/2/18, 123172140, 133182140, 143192140- in use 6/2/18, 123172180, 133182180, 143192180- in use 7/5/18, 123172250, 133182250, 143192250- in use 8/11/18. A demonstration of the DxH 600 hematology analyzer's daily QC review procedures via testing personnel at approximately 2:30 PM revealed that the analyzer could not retrieve daily QC records for the lot number specified above. The analyzer held approximately 6 months data prior to auto-deletion from the hard drive. 4. The technical supervisor confirmed in an interview at approximately 3: 30 PM on February 14, 2019 that the lab could not retrieve the requested hematology QC data.
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 the review of the Laboratory Personnel Report (CLIA) (CMS- 209 Form), policy and procedures (P&P) and an interview with the technical supervisor, the laboratory failed to establish written procedures for competency assessment for individuals performing the job duties of technical supervisor, technical consultant and general supervisor at the dates of survey on February 12-14, 2019. Findings include: 1. The CMS CLIA-209 Form revealed that TP A performs the duties of technical supervisor, technical consultant and general supervisor. (See attached testing personnel code sheet.) 2. Review of the P&P "Lab General Policy and Procedures" (signed by the lab director on 10/03/18) revealed no documentation of a written P&P

	for performing competency assessments for the technical supervisor, general supervisor and technical consultant. 3. An interview with the technical supervisor at approximately 11:30 AM on February 12, 2019 confirmed the findings.
D5449	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(ii)(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 qualitative procedure, include a negative and positive control material; (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: A. Based on the review of policy and procedures (P&P), quality control (QC) test logs, patient test reports, and an interview with the technical supervisor, the lab failed to follow the established procedure for performing 30-day QC procedures for the D-Dimer analyte for six (6) of 12 months in 2017 and resulted a total of one-hundred and five (105) patients. Dates of record review included January 1, 2017 and up to the dates of survey on February 12-14, 2019. Findings include: 1. Review of the P&P "Triage D-Dimer Test" and the Individualized Quality Control Plan (IQCP) for the D-Dimer test system (initial approval on 1/26/16 and annual review on 10/3/18 by the lab director) revealed that the lab will perform external QC materials with each new shipment, new lot number and every 30 days. 2. Review of the Triage D-Dimer QC logs revealed the months in which there was no documentation of the 30-day QC procedures in 2017: February, April, May, July, September and October. 3. Review of the Soft laboratory information system (LIS) patient test report revealed the following patients resulted with no documentation of QC procedures as defined by policy: 02/25 /17- Accession number 94250228, 02/27/17- Accession number 942702955 and 94202042, 04/15/17- Accession number 96150257, 04/16/17- Accession number 961601910, 04/17/17- Accession number 961702537, 04/18/17- Accession number 961802346 and 961805305, 04/19/17- Accession number 961905147, 961901802, 96100824, and 961902666, 04/23/17- Accession number 962302519 and 962303029, 04/26/17- Accession number 962601643, 04/27/17- Accession number 962702450, 04 /29/17- Accession number 962903629, 05/01/17- Accession number 960102334, 05/04 /17- Accession number 970403041, 05/05/17- Accession number 970503499, 05/09 /17- Accession number 970900903, 05/10/17- Accession number 971005553, and 917003312, 05/11/17- Accession number 971106384 and 971102779, 05/12/17- Accession number 971201091, 05/13/17- Accession number 971300898 and 971206396, 05/15/17- Accession number 971500995 and 971502781, 05/17/17- Accession number 971706055, 05/18/17- Accession number 971803310, 05/21/17- Accession number 972100616 and 972101968, 05/22/17- Accession number 972203261, 05/24/18- Accession number 942402867, 05/26/17- Accession number 972603322, 05/27/17- Accession number 972702719, 05/28/17- Accession number 972803193, 07/02/18- Accession number 990104312 07/05/17- Accession number 990505929, 990503592, 990501672, 990503462, and 990503483, 07/06/17- Accession number 990603754, 990602636, 990600802 and 990602008, 07/07/17- Accession number 990703615, 990705489 and 990705906, 07/12/17- Accession number 991206026, 07/17/17- Accession number 991706096, 07/19/17- Accession number 991903376 and 991904297, 07/20/17- Accession number 992003347 and 992003990, 07/22/17- Accession number 992201968 and 992202581, 07/24/17- Accession number 992403854, 07/25/17- Accession number 992503959, 07/30/17-

Accession number 993002640, 09/29/17- Accession number A12905160 and A12904329, 09/30/17- Accession number A13001655, 10/02/17- Accession number A20205689, 10/04/17- Accession number A20405980, 10/07/17- Accession number A20702189 and A20703217, 10/10/17- Accession number A21006147, 10/11/17- Accession number A21106084, 10/13/17- Accession number A21301766, 10/14/17- Accession number A21402649, A21403789, A21403243, and A21403293, 10/18/17- Accession number A21803314 10/19/17- Accession number A21901420, 10/26/17- Accession number A22605643 and A22606198, 10/30/17- Accession number A23006251, 10/31/17- Accession number A23105382, 11/03/17- Accession number A30307071 and A30300844, 11/04/17- Accession number A30403265, 11/07/17- Accession number A30700805, A30703703 and A30700690, 11/08/17- Accession number A3082961, 11/09/17- Accession number A30904240, 11/11/17- Accession number A31005901, 11/12/17- Accession number A31201325, 11/14/17- Accession number A31401209, 11/15/17- Accession number A31500627, 11/19/17- Accession number A31902618, 11/20/17- Accession number A32003423 and A32004962, 11/22 /17- Accession number A32203871, 11/24/17- Accession number A32303744, 11/25 /17- Accession number A32503498, 11/27/17- Accession number A32701713 and A32702635, and 11/28/17- Accession number A32805764 and A32804410. A total of 105 patients. 3. The technical supervisor confirmed the findings in an interview at approximately 2:30 PM on February 13, 2019. B. Based on the review of policy and procedures (P&P), quality control (QC) test logs, patient test reports, and an interview with the technical supervisor, the lab failed to follow the established procedure for performing 30-day QC procedures for the Immunocard STAT! Mono test kit system for twelve (12) of 12 months in 2017 and resulted twenty-nine (29) patients. Dates of record review included January 1, 2017 and up to the dates of survey on February 12-14, 2019. Findings include: 1. The lab utilizes serum samples to assay patient samples for the Immunocard STAT! Mono test kit system, which is categorized as moderate complexity. Review of the P&P " Immunocard STAT! Mono Test" and the Individualized Quality Control Plan (IQCP) for the mono test system (initial approval on 1/26/16 and annual review on 10/3/18 by the lab director) revealed that the lab will perform external QC materials with each new shipment, new lot number and every 30 days. 2. The inspector requested to review the 30-day QC documentation for the calendar year 2017 as outlined by the above-specified policies. The documentation was not available for review. 3. Review of the Soft laboratory information system (LIS) patient test report revealed the following patients resulted with no documentation of QC procedures as defined by policy: 01/01/17- Accession number 930104189, 01/18/17- Accession number 931806796, 01/20/17- Accession number 932002746, 01/24/17- Accession number 932404779, 02/02/17- Accession number 940205689, 02/16/17- Accession number 941604511, 02/18/17- Accession number 941800798, 02/23/17- Accession number 942302995, 03/21/17- Accession number 952104989, 03/22/17- Accession number 952204436, 03/24/17- Accession number 952405172, 05/01/17- Accession number 970103408, 05/07/17- Accession number 970703313, 05/09/17- Accession number 970904505, 05/17/17- Accession number 971704652, 06/19/17- Accession number 981901899, 07/12/17- Accession number 991204901, 08/02/17- Accession number A00203896, 08/06/17- Accession number A00602029, 08/09/17- Accession number A00904942, 08/17/17- Accession number A01705124, 08/23/17- Accession number A02304898, 08/24/17- Accession number A02405650, 09/02/17- Accession number A10203540, 09/25/17- Accession number A12504475, 10/15/17- Accession number A21503405, 10/17/17- Accession number A21703352, 11/01/17- Accession number A30104255 and 11/27/17- Accession number A32705972. Total of 29 patients. 3. The technical supervisor confirmed the findings in an interview at approximately 2:30 PM on February 13, 2019.

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 the review of policy and procedures (P&P) and interview, the lab failed to follow the established policy for reviewing monthly chemistry and hematology quality control statistics for twenty-four (24) of 24 months reviewed during the dates of survey on February 12-14, 2019. Dates of record review includes January 1, 2017 through December 31, 2018. Findings include: 1. Review of the P&P "Quality Control Procedures and Review", signed by the lab director on 10/4/2018, revealed the following statements: "Chemistry- The mean and SD should be reviewed at the end of each month and changes made as necessary to account for variations in lot-to-lot and control materials. Changes in the mean and SD should be noted each month on the QC summary sheet." "Hematology- 6.0 Notes- Controls are reviewed and acceptable prior to reporting patient results. QC statistics are viewed monthly by Lab Service Manager and pathologist." 2. The inspector requested to review the QC summary sheets for chemistry and hematology for 2017 and 2018. The documentation was not available for review. 3. During an interview with the technical supervisor at approximately 3:30 PM on February 14, 2019, she/he stated that the QC and statistical reviews are performed via the instrument(s) computer and that there was no printed or written documentation of review.
D6095	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(6) The laboratory director must ensure the establishment and maintenance of acceptable levels of analytical performance for each test system. This STANDARD is not met as evidenced by: Based on the review of policy and procedures (P&P), available quality control (QC) records, manufacturer package inserts (PI), instrument test data, patient test reports, and interview with the technical supervisor, the lab director failed to ensure analytic procedures were maintained from January 1, 2017 and up to the dates of survey on February 12-14, 2019 (Cross Reference D3031, D5449, and D5791).
D6120	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(7)(8) (7) The technical supervisor is responsible for identifying training needs and assuring that each individual performing tests receives regular in-service training and education appropriate for the type and complexity of the laboratory services performed; (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 the review of the Laboratory Personnel Report Form (CLIA) (CMS-209 Form), testing personnel (TP) records, and interview with the technical supervisor, the technical supervisor failed to sign the competency assessments of three (3) of the 13 competency assessments performed in 2018. Dates of record review include 2017 and 2018 assessments. Findings include: 1. Review of the CLIA CMS 209 form revealed that there are 13 TP performing patient testing and that TP A performs the duties of technical supervisor (See attached testing personnel code sheet). 2. Review of 2017 and 2018 competency assessments revealed the lack of signature and review by the technical supervisor for the following: - TP B- 2018 annual competency assessment, - TP C- 2018 annual competency assessment, - TP D- 2018 initial (performed on 4/30/2018) and semi-annual (10/22/2018) competency assessment. 3. The technical supervisor confirmed the findings in an interview at approximately 2:30 PM on February 12, 2019.