Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	49D2148336	10/04/2024
Name of Provider or Supplier	**Street Address, City, State**	
Community Access Network	800 5th Street, Suite A, Lynchburg, 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 unannounced onsite Clinical Laboratory Improvement Amendments (CLIA) complaint investigation (Complaint #VA00061839) was conducted at Community Access Network on October 2, 2024 by a Medical Facilities Inspector from the Virginia Department of Health, Office of Licensure and Certification. The investigation included a tour, review of procedures, quality control, temperature monitoring, and maintenance logs, testing personnel records, and interviews with the facility Clinical Lead and Information Technology Coordinator. The complaint investigation also included an offsite exit interview with the Laboratory Director on 10 /04/24. The laboratory was surveyed under 42 CFR part 493 CLIA Regulations. The specific deficiency cited is as follows:
D5983	PPM LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1359 The laboratory director is responsible for the overall operation and administration of the laboratory, including the prompt, accurate, and proficient reporting of test results. This STANDARD is not met as evidenced by: Based on a tour, review of the laboratory's policy and procedure manual, manufacturer's user guide, Centers for Medicare and Medicaid Services Laboratory Personnel Report form (CMS 209), testing personnel (TP) records, lack of documentation, and interviews, the laboratory director (LD) failed to ensure that the quality assurance (QA) protocols of TP training/competency assessment documentation were followed for ten (10) of 10 TP during the twenty-two (22) months of review (January 2023 to 10/2/24). Findings include: 1. During a tour of the laboratory at 10 AM on 10/02/24, the inspector noted the following analyzer/test kits in use: Quick View In Line Rapid Strep A, Quidel Sofia Strep A-FIA, SARS COV-2, Influenza A, B, Abbott Binax Now Respiratory Syncytial Virus (RSV), Alere Urine Pregnancy Human Chorionic Gonadotropin, Accu-check Performa Glucose, Abbott Affinion Dx Glycated Hemoglobin A1c, Siemens Urinalysis Siemens Urine

	Microalbumin, Megellan LeadCare Blood Lead, McKesson Drugs of Abuse Test Cups (UDS), Hemocue Hemoglobin. The inspector noted one microscope with dust cover located in the laboratory. 2. Review of the laboratory's policy and procedure manual revealed a QA policy that outlined: Section- QA Personnel: "The site will maintain documentation and records of training and competency. All personnel assigned any laboratory testing duties must have training appropriate to those duties. The initial evaluation of new personnel will be done during orientation in the laboratory and documentation will be performed. This evaluation should include review of test procedures performed, specimen handling and processing, quality control testing and recording, results recording and interpretation, instrument maintenance, assessment of problem-solving skills, and safety guidelines." Section- QA Competency Assessment: "Evaluating competency of all testing personnel is to ensure staff maintain competency to perform test procedures and report accurately. This is ongoing process which will be documented twice per year during the first year and annually thereafter." 3. Review of the Quidel Sofia 2 Users Guide revealed a manufacturer provided training quiz for testing personnel (TP). The user guide stated, "This quiz is an educational tool intended to assist facilities in evaluating their operators' understanding of the assay(s) tested. This quiz is not intended to be used as sole evidence of operator training or competency. Facilities are responsible for ensuring the quality of the testing performed by their operators." 4. Review of the CMS 209 form revealed that the LD identified 10 TP qualified for the performing rapid point of care testing outlined above during the 22 months of review (January 2023 to 10/2/24). The inspector inquired which of the listed TP performed microscopy procedures. The Clinical Lead stated on 10/2/24 at 1:30 PM, "No one has used the microscope in the last two years as far as I am aware." The Information Technology (IT) Coordinator stated on 10/2/24 at 1:30 PM, "We had a provider in the past that said they wanted the microscope but they never used it and now they are no longer here." 5. The inspector requested to review TP #1 - TP #10 personnel files with records of education, training, and competency assessments per the laboratory policy for the 22 months of review. No training/competency records were available for TP #1 - TP #10. See Personnel Code Sheet attached. 6. An exit interview with the LD on 10 /04/24 at approximately 2:00 PM confirmed the above findings.