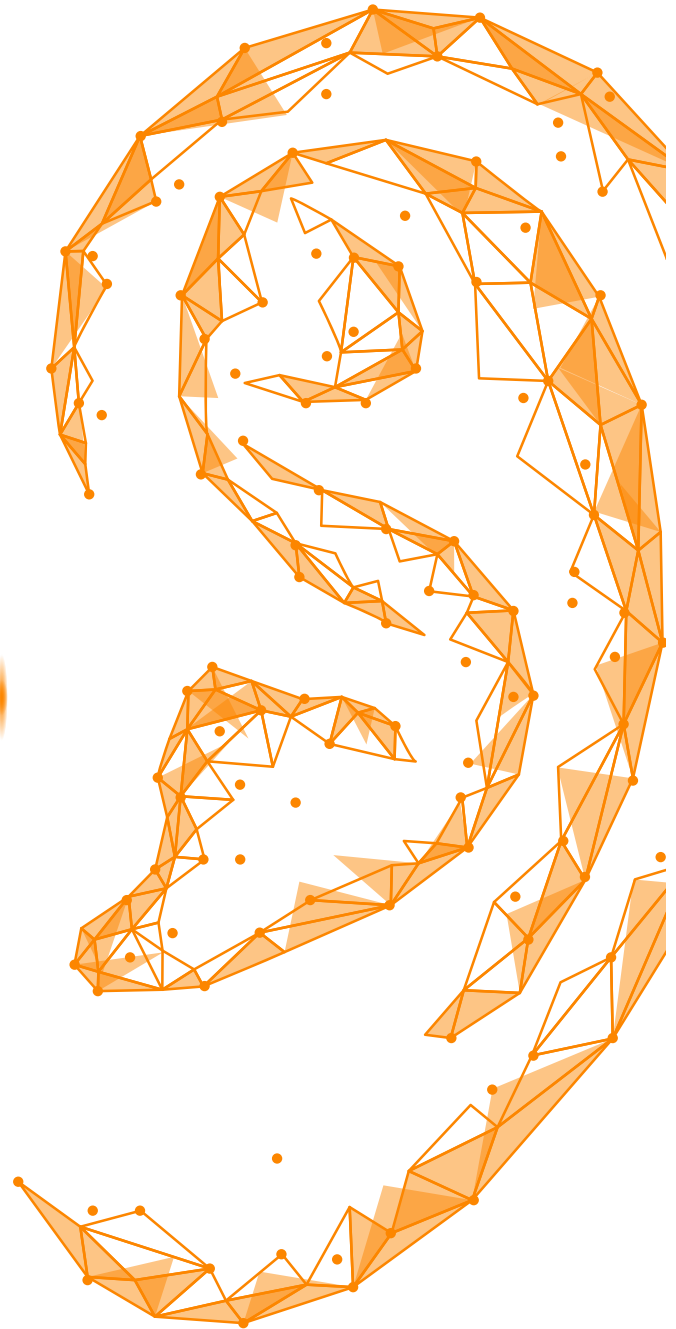
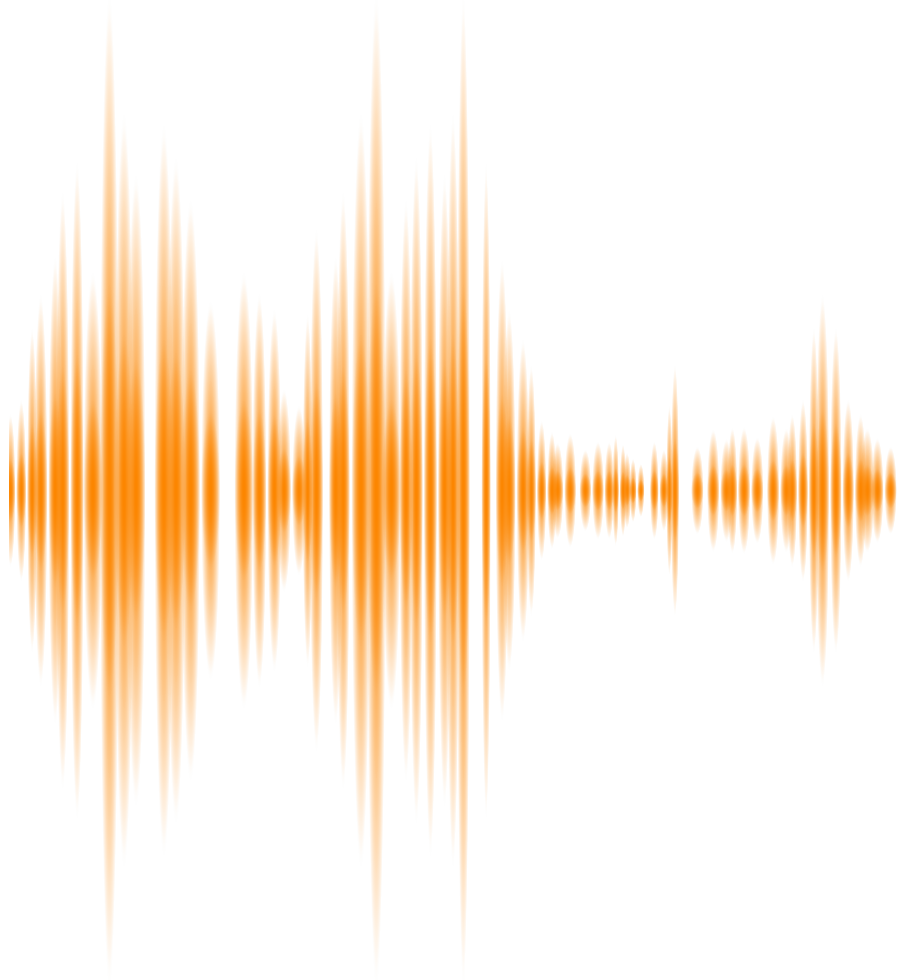


Virginia Early Hearing Detection & Intervention Program

HEARING TARGETED CONGENITAL CYTOMEGALOVIRUS (cCMV) SCREENING PROTOCOLS



2020



**Hearing Targeted Congenital Cytomegalovirus (cCMV) Screening Protocols
Virginia Early Hearing Detection and Intervention Program
Virginia Department of Health**

This document provides guidance and recommended procedures how best to implement requirements that are specified in the *Code of Virginia*, Section 32.1-64 12VAC5-80-150¹ and *Regulations for the Administration of the Virginia Hearing Impairment Identification and Monitoring System*²

These protocols represent the best practices and recommendations by the Virginia Early Hearing Detection and Intervention (VA EHDI) Program Advisory Committee (AC) for hearing targeted congenital Cytomegalovirus (cCMV) screening. The VA EHDI AC, which consists of representatives from relevant groups including, but not limited to, physicians, otolaryngologists, audiologists, speech pathologists, nurses, parents and educators of the deaf and the hard of hearing, unanimously agreed that Virginia’s Hearing Targeted cCMV Screening Protocols are an exceptional model of evidence-based practice and should reflect an excellence beyond minimal standards of care. This document reflects that philosophy.

One out of three pregnant women infected with Cytomegalovirus (CMV) will pass the virus to their unborn child. With 1 in 200 children being born with cCMV each year, it is the most common intrauterine infection and the number one non-genetic cause of hearing loss in the United States. It is important to recognize that hearing targeted cCMV screening is only one component of a comprehensive approach to the diagnosis and management of a child with cCMV and/or congenital hearing loss. The comprehensive process should involve a multidisciplinary team including, but not limited to physicians, nurses, audiologists, and parents. This document, therefore, highlights key information about which stakeholders should be aware and addresses children with otherwise asymptomatic cCMV who have failed their hearing screening.

I. Birthing Hospital Responsibilities

1. Hospitals should designate a minimum of two hospital employees who are primarily responsible for the hearing targeted cCMV screening program in that facility. These individuals should act as the primary points of contact between the facility and VA EHDI and should gain access to the Virginia Infant Screening and Infant Tracking System (VISITS) database.

¹ To access the Code of Virginia citation, go to: <https://law.lis.virginia.gov/admincode/title12/agency5/>

² To access the Regulations for the Administration of Virginia Hearing Impairment Identification and Monitoring System, go to: <https://law.lis.virginia.gov/admincode/title12/agency5/chapter80/>

2. Hospitals should develop methods for collecting and recording all required data that assure data quality. Additionally, hospitals should ensure strict quality control standards for adhering to reporting requirements, especially in those hospitals where staff who perform the screening are different from staff who enter and record the data. Information regarding screening status should be a permanent part of the patient's medical record.
3. Training and quality assurance measures are vital components for the efficiency and overall effectiveness of screening programs. Hospitals should ensure that all screening personnel are appropriately trained to carry out the cCMV screening using appropriate methods. Hospitals should ensure training records are maintained.
4. Hospitals are required to:
 - i. Provide written information to the parent that includes the benefits of cCMV screening and recommendations for further testing.
 - ii. Inform the parent in writing prior to discharge that their child received a cCMV screening, including the recommendations for follow up (per Regulation).
 - iii. Communicate as soon as possible to the Primary Care Provider (PCP) from whom the infant will receive care after discharge (per Regulation) that the child:
 - Received cCMV screening;
 - Missed hearing and cCMV screening; or
 - Had failed outpatient initial hearing but missed cCMV screening.
 - iv. Once the results of the cCMV screening are received, communicate results to the PCP.
 - v. Communicate to the family the importance of medical and developmental follow-up, the importance of contacting their child's PCP with any developmental concern, and the benefits of the early identification of cCMV.
5. Once a year, VDH will notify hospitals to complete and return to VDH an annual reporting form.

II. In-Patient Screening

All infants who have failed final newborn hearing screening at birth, must receive a cCMV screening by 21 days of life and prior to hospital discharge to home. If the child has a failed final newborn hearing screening after 21 days of life consider consulting with Pediatric Infectious Disease Specialist to discuss next steps. Even if the infant had a hearing screen at a previous facility, the discharge to home hospital should perform a cCMV screening by 21 days of life, as the infant's health status may have changed.

Testing Parameters:

- Ensure that results of hearing screening are communicated to the medical provider responsible for conducting the cCMV screening.
- Hospitals should develop internal guidelines on:
 - Communicating hearing screening results and information on cCMV screening to medical providers and parents.
 - Who will conduct the cCMV screening.
 - Whether a standing order policy is adopted in order to reduce delay and improve compliance.

Specimen Collection and Preparation:

- Sample type: Neonatal saliva swab.
 - Saliva flocked swabs can be collected dry and placed in a tube for transport to the Division of Consolidated Laboratory Services (DCLS). Flocked swabs are ideal for molecular testing due their structure, which allows for better cell collection. They are also gentle enough for use on newborns. The flocked swab must NOT have a wooden shaft and the entire swab must be inserted into a tube for transport.
 - Example – Copan Diagnostics 516C.BX Pediatric tip
- Sample Collection:
 - Collect saliva swab samples and place into a transport tube according to established laboratory methods.
 - This video outlines the collection process:
https://www.meridianbioscience.com/human-condition/pediatric_neonatal/cmva/alethia-cmv/
 - NOTE: No special preparation of the neonate is required in order to collect the sample; however, if the infant is taking breastmilk, the saliva swabs should be collected at least one hour after feeding.
 1. Open a sterile flocked swab and remove it from the transport tube.
 2. Place swab between baby’s cheek and gum and swab gently, allowing the swab to remain in contact with the gum for 10-15 seconds.
 3. Move swab to other side of the baby’s mouth and repeat, allowing the swab to remain between cheek and gum for 10-15 seconds.
 4. Check to ensure the swab appears moistened when removed from the baby’s mouth.
 5. Ensure tube is labeled appropriately as directed by VDH.
 6. Replace the swab into the tube for storage and transport.
- Sample Storage:
 - Saliva swabs must be stored refrigerated (2-8 degrees C) after collection and during transportation to the laboratory.
- Sample transport:

- Samples should be sent via courier to DCLS for testing within 24 hours of collection. Complete sample submission form provided.
 1. Place swab in tube in biohazard bag (provided by DCLS), ensuring tube is labeled appropriately.
 2. Seal bag by removing adhesive strip and pressing adhesive to the plastic bag.
 3. Insert completed “DCLS Blood and Body Fluid” submission form into pocket on front of biohazard bag.
 4. Place bag containing tube and form on frozen ice pack in cooler (provided by DCLS).
 5. Place cooler in courier pick up area near courier pick up time.
 6. Check to ensure sample was picked up after courier visit. If not, return swab to the refrigerator until next courier pick up.
- Materials:
 - DCLS provided kit components – (to order more please contact DCLS (804) 648-4480 (ext 104))
 - Cooler, Biohazard bags, Ice packs,
 - Electronic Order form and label will be generated using VISITS.
- **Primary Care Provider Responsibilities**
 1. Primary Care Providers (PCP) should ensure that children who have failed initial hearing screening have received cCMV screening in the hospital by 21 days of life.
 2. PCP should review results of cCMV screening and provide recommendations based on results.
 - Inconclusive results on cCMV Screening
 - Ensure child has a urine CMV Polymerase Chain Reaction (PCR) immediately upon receipt of test results within 21 days of life.
 - PCP should ensure appropriate specimen collection parameters: ex- may use urine bag, but not cotton balls or gauze as it can inhibit PCR reaction.
 - PCP should consider consulting with Pediatric Infectious Disease Specialist.
 - Positive results on cCMV Screening with saliva PCR
 - Ensure child has a urine cCMV PCR immediately upon receipt of test results within 21 days of life.
 - PCP should ensure appropriate specimen collection parameters: ex- may use urine bag, but not cotton balls or gauze as it can inhibit PCR reaction.

- PCP should consider consulting with Pediatric Infectious Disease Specialist.
- Missed cCMV screening
 - Refer for outpatient cCMV saliva swab or urine CMV PCR screen or obtain and send either saliva or urine for CMV PCR immediately upon notification of missed screening within 21 days of life.
 - If child is over 21 days of life consider consulting with Pediatric Infectious Disease Specialist to discuss next steps.
 - PCP should consider consulting with Pediatric Infectious Disease Specialist.
- 3. PCP should consider consulting with and referring to Infectious Disease Specialist for medical management of infants who have test results suggesting cCMV.
- 4. Visit www.vdhivewell.com/ehdi for information on regional Infectious Disease Specialists, regional Otolaryngologists, and pediatric Audiology facilities for more information on cCMV management.

IV. Audiology Provider Responsibilities

1. Audiologists should report failed results on hearing screen to PCP and VDH immediately.
2. Audiologists should refer children who have failed initial hearing screening in their office to PCP for cCMV screening and further education on cCMV.
3. Audiologists should refer to Virginia EHDI Intervention Protocols for Audiologists on recommendations for conducting hearing screening and/or diagnostic testing.

V. Reporting

1. Reporting should be done through the VISITS database as managed by VDH. The hospital should notify VDH that a cCMV screening was completed within seven days of discharge, however, best practices recommend reporting within 48 – 72 hours of discharge.
2. If a VISITS user is no longer employed by the hospital, please notify VA EHDI immediately. For the reporting system to function optimally, use of Internet Explorer 10 or 11 or Google Chrome is required.

VI. Virginia Department of Health Responsibilities

1. VDH shall provide education to parents and stakeholders on cCMV prevention and next steps after diagnosis.
2. VDH should contact the parent and/or guardian of children who are screened for cCMV and provide recommendations for next steps.
3. VDH should contact parent and/or guardian of children for children who test positive on cCMV screening and provide recommendations for next steps.

4. VDH should contact the PCP to inform them of children who screen positive on cCMV screening and discuss next steps.

For more information or further assistance, contact:

Virginia Department of Health
Office of Family Health Services
Virginia Early Hearing Detection and Intervention Program
109 Governor Street, 9th Floor
Richmond, Virginia 23219
Phone: Toll Free 1-866-493-1090 TTY 7-1-1
Fax: 804-864-7771
Website: newbornhearingtestva.com

If a VISITS user is locked out of VISITS, please call the help desk at (804) 864-7200 option 2 between 8:00 am – 5:00 pm or use the forgot password link at the login page to reset your password.

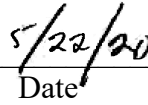
For technical and reporting issues, such as inability to locate a child, please contact the VA EHDI staff at va_ehdi@vdh.virginia.gov.

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Approved by:



M. Norman Oliver, MD, MA
State Health Commissioner


Date



 VDHLiveWell.com/EDHI