ACUTE VIRAL GASTROENTERITIS LABORATORY TESTING GUIDANCE

<table>
<thead>
<tr>
<th>Appropriate Clinical Specimens for Laboratory Testing*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Testing Method</td>
</tr>
<tr>
<td>PCR §†</td>
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</tbody>
</table>

*PCR testing is intended primarily for surveillance and to support epidemiological investigations.

§ Vomitus will not be accepted without prior consultation.
† When submitting norovirus positive stools for strain typing, norovirus positive viral RNA extracts may be included if available. Do not send RNA extract without an accompanying stool UNLESS stools are not available.
¶ Sequence analysis for strain typing will be performed on PCR-positive specimens with sufficient viral loads.

Outbreaks of Gastroenteritis are reportable under the Title 17, California Code of Regulations. Health care providers must contact their local public health department to report outbreaks. A number of local public health laboratories provide norovirus RT-PCR testing services. Please contact your local health jurisdiction for more information.

Causative Agents of Acute Viral Gastroenteritis

- Norovirus causes approximately 50% of acute viral gastroenteritis outbreaks and 90% of epidemic gastroenteritis.
- Other viral causes of acute gastroenteritis include: sapovirus, rotavirus, adenovirus types 40 and 41, and astrovirus

Clinical Specimen = Stool

- Ideally, stool specimens should be obtained during the acute phase of illness (within 48-72 hours of diarrhea onset) while the stools are still liquid or semisolid and the level of virus excretion is greatest.
- Increased sensitivity of molecular assays (e.g., PCR) often allows the virus to be detected in stools collected up to 7-10 days after illness onset.
- For specimens collected after 10 days of illness, the utility of viral diagnosis and interpretation of the test results should be discussed with laboratory personnel before tests are conducted.

Number of Samples to Collect

- For suspected viral gastroenteritis outbreaks, collect at least three (3) stool samples, up to a maximum of ten (10) stool samples. Three samples is the optimal minimum. See Interpretation of Laboratory Results below.
- For confirmed norovirus outbreaks submitted for strain typing, submit a minimum of two (2) and a maximum of four (4) positive stools along with their RNA extracts to the Viral and Rickettsial Disease Laboratory (VRDL) for typing
  - A single stool sample will not be tested since neither a positive nor negative result will be meaningful.
  - Testing of asymptomatic cases is not encouraged without prior consultation.

Questions about specimen collection, submittal, or shipping: Contact the VRDL Medical and Epidemiology Liaison Section at (510) 307-8585 for more information.
Specimen storage and shipping

- Stool specimens should be refrigerated at 4°C until they can be sent to the laboratory. Specimens can be stored at 4°C for up to 2-3 weeks. Store at -70°C or colder for longer periods.
- Store RNA extracts at -70°C or colder.
- Stools can be shipped overnight on cold packs. Ship RNA extracts to VRDL on dry ice.

Interpretation of Laboratory Results

- Norovirus PCR testing is intended for use primarily for surveillance and to support epidemiological investigations.
- CDC interpretative guidelines for suspected outbreaks based on laboratory PCR results are as follows:
  - **POSITIVE** - Norovirus can be considered to be the etiologic agent if norovirus nucleic acid is detected in two (2) or more stools per outbreak.
  - **NEGATIVE** - To be considered as a Norovirus negative outbreak, at least 3 or more acute stool samples (all collected with 7-10 days of onset of diarrhea) must be submitted and all 3 must be negative for norovirus nucleic acid.
  - **INCONCLUSIVE** - All other outcomes.

Specimen shipments to VRDL require prior approval by the local public health department. With local public health department approval, specimens may be shipped directly to the VRDL.

- Complete the VRDL Outbreak Summary Form (https://tinyurl.com/yc4m2uva) and send along with the individual submittal forms.
- Complete the VRDL General Specimen Submittal Form for each specimen (https://tinyurl.com/yaxmf3bz).
  - If specimens are from a PCR-confirmed outbreak please indicate the genogroup result as either “GI”, “GII” or mixture of “GI+GII” and include CT values.

Ship approved specimens to:

ATTN: Specimen Receiving, CDPH VRDL
850 Marina Bay Parkway Richmond, CA 94804