## APPENDIX 2: SCHEDULE OF EVENTS: SCREENING, ACUTE PHASE (STUDY DAYS 0 TO 28), AND POST-ACUTE PHASE (STUDY DAY 29 TO THE DAY 56 VISIT)

<table>
<thead>
<tr>
<th>Day Number</th>
<th>Day 0</th>
<th>Day 1&lt;sup&gt;+&lt;/sup&gt;</th>
<th>2&lt;sup&gt;+&lt;/sup&gt;</th>
<th>3</th>
<th>4&lt;sup&gt;+&lt;/sup&gt;</th>
<th>5</th>
<th>6&lt;sup&gt;+&lt;/sup&gt;</th>
<th>7</th>
<th>8&lt;sup&gt;+&lt;/sup&gt;</th>
<th>9&lt;sup&gt;+&lt;/sup&gt;</th>
<th>10</th>
<th>11&lt;sup&gt;+&lt;/sup&gt;</th>
<th>12</th>
<th>13&lt;sup&gt;+&lt;/sup&gt;</th>
<th>14</th>
<th>15&lt;sup&gt;+&lt;/sup&gt;</th>
<th>16&lt;sup&gt;+&lt;/sup&gt;</th>
<th>17</th>
<th>18&lt;sup&gt;+&lt;/sup&gt;</th>
<th>19</th>
<th>20&lt;sup&gt;+&lt;/sup&gt;</th>
<th>21</th>
<th>22-27&lt;sup&gt;+&lt;/sup&gt;</th>
<th>28</th>
<th>29&lt;sup&gt;+&lt;/sup&gt;</th>
<th>Day 56 Visit</th>
<th>Sick Visit</th>
<th>Early DC</th>
</tr>
</thead>
<tbody>
<tr>
<td>Visit Windows (days)</td>
<td>-42</td>
<td>±1</td>
<td>±1</td>
<td>±1</td>
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<tr>
<td>Informed Consent</td>
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<tr>
<td>History / Physical exam</td>
<td>X&lt;sup&gt;2&lt;/sup&gt;</td>
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<td>Interim History&lt;sup&gt;3&lt;/sup&gt;</td>
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<tr>
<td>Study product administered &lt;sup&gt;4,5&lt;/sup&gt;</td>
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<tr>
<td>Clinical assessment&lt;sup&gt;6&lt;/sup&gt;</td>
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<td>X</td>
<td>X</td>
<td>X</td>
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<tr>
<td>Blood for immunologic assays</td>
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<tr>
<td>Nasal wash for antibody</td>
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<tr>
<td>Nasal wash for viral detection &amp; quantification&lt;sup&gt;7&lt;/sup&gt;</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
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</tbody>
</table>

**Footnotes**

1. Window for this visit is up to 42 days prior to planned inoculation (Day 0). Day 0 should occur within 3 days of randomization per Section 5.15.
2. Medical history including demographics, prior diagnoses, current medications, signs and symptoms, and developmental status. Complete physical exam including temperature, heart rate, respiratory rate, weight, length and assessment of HEENT [Head, Ears, Eyes, Nose, Throat], lungs, heart, abdomen, musculoskeletal, age-appropriate neurological and skin exam.
3. If in-person visit is moved by ±1 day, then telephone contact is done in place of the original interim visit date. At visits conducted by phone or email, document temperature values as collected by parents/guardians on the temperature card. See Sections 6.13 and 6.14.
4. Study product is to be administered within 4 hours after removal from the freezer (see Manual of Procedures [MOP]).
5. Study product administered after Day 0 nasal wash obtained (see MOP).
6. Clinical assessment includes focused clinical examination (including temperature, heart rate, respiratory rate, HEENT, lungs, heart, and lymph nodes). On Study Day 28, also review with parent/guardian illness criteria and when to contact study personnel during Study Day 29 to the Day 56 Visit. Clinical assessment must be done by medical professional.
7. Nasal wash for viral culture for RSV sent to central laboratory (see Laboratory Processing Chart [LPC]). If illness criteria met or suspected (see Section 6.15, Section 6.21, and Appendix 4), complete adventitious agent assay request for rRT/PCR for adventitious agents (see MOP).
8. Non-Visit Day (Study Day 1, 2, 4, 6, 8, 9, 11, 13, 15, 16, 18, 20, 22-27, 29) information collected by telephone or email contact.
9. For symptoms of LRI during the Acute Phase and Post-Acute Phase, the Sick Visit must occur within 24 hours. For fever, otitis media, or URI (per Appendix 4) during the Acute Phase, the Sick Visit must occur within 3 days if Grade 1 and within 2 days if Grade ≥ 2. See Section 7.7 for Protocol Pausing and Stopping Rules.
10. See Appendix 4 for definitions of illness. LRI signs should be confirmed by a second medical professional if possible.
APPENDIX 3: SCHEDULE OF EVENTS: RSV PRE-SEASON SAMPLING, SEASONAL SURVEILLANCE, AND POST-SEASON SAMPLING

<table>
<thead>
<tr>
<th>Visit Windows</th>
<th>Pre-RSV season&lt;sup&gt;1&lt;/sup&gt;</th>
<th>Weekly report&lt;sup&gt;2&lt;/sup&gt;</th>
<th>Sick Visit&lt;sup&gt;3&lt;/sup&gt;</th>
<th>Post-RSV season&lt;sup&gt;5&lt;/sup&gt;</th>
<th>Early DC</th>
</tr>
</thead>
<tbody>
<tr>
<td>History / Clinical assessment</td>
<td></td>
<td></td>
<td></td>
<td></td>
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</tr>
<tr>
<td>Interim history</td>
<td></td>
<td>X</td>
<td>X</td>
<td></td>
<td>X</td>
</tr>
<tr>
<td>Blood for immunologic assays</td>
<td>5 mL</td>
<td></td>
<td></td>
<td>5 mL</td>
<td></td>
</tr>
<tr>
<td>Nasal wash for viral detection &amp; quantification&lt;sup&gt;4&lt;/sup&gt;</td>
<td></td>
<td></td>
<td>X</td>
<td></td>
<td></td>
</tr>
<tr>
<td>TOTAL BLOOD VOLUME</td>
<td>5 mL</td>
<td>--</td>
<td>--</td>
<td>5 mL</td>
<td>5 mL</td>
</tr>
</tbody>
</table>

Footnotes
1. Visit and sample not required if Study Day 56 visit occurs after October 1<sup>st</sup>.
2. Telephone, email or in person contact weekly to obtain interim history and arrange for study visit if child meets illness criteria for Sick Visit.
3. Sick visit within 3 days of site notification if child has a medically attended illness of the following types: fever, upper or lower respiratory illness, or otitis media.
4. Sick Visit includes nasal wash for viral culture for RSV and adventitious agents (respiratory viruses) by multiplex rRT-PCR within 3 days of site notification.
5. At post-RSV season in-person visit, obtain serum antibody specimen and advise parent/guardian of study randomization, if known.

**Protocol-Required Non-Standard Reagents and Supplies**

<table>
<thead>
<tr>
<th>Evaluation</th>
<th>Reagent or Supply</th>
<th>Manufacturer part #</th>
<th>Company</th>
</tr>
</thead>
<tbody>
<tr>
<td>Snap Freezing either workstation can be used, one hold 30 vials the other 24 vials</td>
<td>CoolBox XT System</td>
<td>BCS-575</td>
<td>(BioCision LLC or Fisher Scientific)</td>
</tr>
<tr>
<td></td>
<td>CoolBox 30 System</td>
<td>BCS-166</td>
<td></td>
</tr>
<tr>
<td>Snap Freezing</td>
<td>Sarstedt 2ml Cyrovials</td>
<td>72.694.006</td>
<td>(Sarstedt or Fisher Scientific)</td>
</tr>
<tr>
<td>Nasal Wash Antibody storage</td>
<td>4.5ml Cyrovials</td>
<td>NUNC (347643) or Fisher Scientific (12-565-299) or equivalent</td>
<td></td>
</tr>
<tr>
<td>Nasal Wash</td>
<td>Viral Transport Media (VTM)</td>
<td>N/A</td>
<td>JHU see map for ordering instructions</td>
</tr>
</tbody>
</table>
### Section 3 (SCREENING. ACUTE AND POST-ACUTE): Specimen Processing & Shipping Instructions

<table>
<thead>
<tr>
<th>Evaluation</th>
<th>Tube Type</th>
<th>Special Collection Notes</th>
<th>CRF # DMC Test Code</th>
<th>Processing</th>
<th>Shipping</th>
</tr>
</thead>
<tbody>
<tr>
<td>Serum storage for Immunologic Assays (Serum RSV Ab)</td>
<td>NON or SST</td>
<td>Must be collected prior to vaccine administration.</td>
<td>CRF: f3008 DMC Test Code: ABRSVQT</td>
<td>Allow to clot for at least 30 mins. Spin blood at 1000xg for 10 mins; remove serum and save at least 3 X 0.5mL aliquots and freeze at -80°C.</td>
<td>Screen- Ship ONE aliquot real time M-W to JHU, retain the remaining aliquots on site until requested by team. For Day 56 samples: Ship ONE aliquot to JHU, multiple patient samples can be batched and shipped within 2 weeks of that time point, retain the remaining aliquots on site until requested by team. Ship samples on dry ice priority overnight, M-W only</td>
</tr>
<tr>
<td>Nasal Wash (NW) for RSV Antibody</td>
<td>Nasal Wash</td>
<td>After collection, keep Nasal wash refrigerated or on wet ice until processed and frozen. See P2000 MOPS for detailed NW collection instructions</td>
<td>CRF: f3008 DMC Test Code: ABRSVQT</td>
<td>Measure and save 6 mL NW from total sample to be used for Viral Detection and Quantification. Aliquot all remaining NW in 2 equal (2-4 mL) aliquots for RSV AB assay. If volume exceeds 8 mL, prepare additional 2-4 mL aliquots. Nasal Washes for RSV Antibody must be kept on wet ice until processed or alternatively can be snap frozen with RSV for viral detection sample. Store at --80°C Use Nunc starfoot vials, external thread, 4.5 ml. NOTE Nasal wash aliquots for RSV Antibody do not contain VTM.</td>
<td>Day 0 Ship ONE aliquot to JHU at the end of the acute phase (Day0-28) Day 56 Ship ONE aliquot to JHU, multiple patient samples can be batched and shipped within 2 weeks of the time points, unless directed to ship sooner by team. Retain the 2nd aliquots on site until requested by team. Ship all samples on dry ice priority overnight, M-W only</td>
</tr>
</tbody>
</table>
### Section 3 (SCREENING. ACUTE AND POST-ACUTE): Specimen Processing & Shipping Instructions

<table>
<thead>
<tr>
<th>Evaluation</th>
<th>Tube Type</th>
<th>Special Collection Notes</th>
<th>CRF # DMC Test Code</th>
<th>Processing</th>
<th>Shipping</th>
</tr>
</thead>
<tbody>
<tr>
<td>Nasal Wash for RSV Viral Detection and Quantification (and/or rtPCR for adventitious agents)</td>
<td>Nasal Wash</td>
<td>After collection, keep Nasal wash refrigerated or on wet ice until processed and frozen. See P2000 MOPS for detailed NW collection instructions. Nasal wash for RSV viral detection must be mixed with Viral Transport Media (VTM), aliquoted and snap frozen within 30 min of collection.</td>
<td>CRF: F3008 DMC Test Code: CXRSVQT and/or ADVENTTS</td>
<td>Sterilely Transfer 6mL of Nasal Wash into vial containing 1.5 mL cold (2-8°C) VTM. Gently mix to assure even distribution of specimen in VTM. Aliquot into 7 X 1.0mL aliquots (Sarstedt 2ml cryovials) Be sure cap is on tight, and then flash freeze in Blicision Coolbox, for a minimum of 15 min. Transfer frozen aliquots immediately to -80°C freezer. See specific freezing instructions in MOPS.</td>
<td>Ship FOUR aliquot to JHU at the end of the acute phase, on dry ice priority overnight, M-W only. Retain 3 aliquots on site until requested by team. Multiple patient samples can be batched and shipped within 2 weeks of the time points, unless directed to ship sooner by team. NOTE: If febrile or respiratory illness criteria are met or suspected, sample must be shipped real time for adventitious virus assay. Include copy of F3008 with shipped samples. Please notify JHU of any changes made to LDMS or the F3008 form after the sample has been shipped. NOTE: Lab must enter comment in LDMS for all aliquots that have a different time on label than in the LDMS (for example: “LDMS time is actual sample time as noted on CRF. Time on label is not correct.”)</td>
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</tbody>
</table>
### Section 4 APPENDIX 2 (SCREENING, ACUTE AND POST-ACUTE PHASE):

**SCREEN:** Window for this visit is up to 42 days prior to vaccination (Day 0).

<table>
<thead>
<tr>
<th>Evaluation</th>
<th>Specimen</th>
<th>CRF</th>
<th>Aliquots</th>
<th>LDMS Code</th>
<th>Special Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Serum storage for Immunologic Assays (Serum RSV AB)</td>
<td>5 mL NON or SST</td>
<td>F3008</td>
<td>Save all SER in at least 3X0.5 ml aliquots</td>
<td>BLD/NON/SER OR BLD/SST/SER</td>
<td>NOTE: One screening serum aliquot must be shipped to JHU real time.</td>
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<td></td>
<td>Blood</td>
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**ENTRY DAY 0:** Day 0 should occur within 3 days of randomization per section 5.1.5

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<th>Evaluation</th>
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<th>CRF</th>
<th>Aliquots</th>
<th>LDMS Code</th>
<th>Special Notes</th>
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</thead>
<tbody>
<tr>
<td>Nasal Wash for RSV Antibody</td>
<td>Nasal Wash</td>
<td>F3008</td>
<td>Remove 2 equal 2-4mL aliquots and store at -80°C. Save all nasal wash. See MOPs for additional instructions.</td>
<td>NPW/RLS/NPW</td>
<td>Nasal Washes for RSV Antibody must be kept on wet ice until processed or alternatively can be snap frozen with RSV for viral detection sample. NOTE: Nasal wash for antibody does not have the addition of VTM.</td>
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</tr>
<tr>
<td>Nasal Wash for RSV Viral Detection and Quantification (and/or rtPCR for adventitious agents)</td>
<td>Nasal Wash</td>
<td>F3008</td>
<td>Divide into 7x1.0mL aliquots, snap freeze and store at-80°C.</td>
<td>NPW/RLS/NPW/VTM</td>
<td><strong>Nasal Washes for RSV viral detection must be processed and snap frozen within 30 min of collection.</strong> If sample cannot be received and processed in lab within this time, must be processed at the collection site.</td>
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</table>

**DAY 3, 5, 7, 10, 12, 14, 17, 19, 21, or 28 (±1 days)**

<table>
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<tr>
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<th>Specimen</th>
<th>CRF</th>
<th>Aliquots</th>
<th>LDMS Code</th>
<th>Special Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Nasal Wash for RSV Viral Detection and Quantification (and/or rtPCR for adventitious agents)</td>
<td>Nasal Wash</td>
<td>F3008</td>
<td>Divide into 7x1.0mL aliquots, snap freeze and store at-80°C.</td>
<td>NPW/RLS/NPW/VTM</td>
<td><strong>Nasal Washes for RSV viral detection must be processed and snap frozen within 30 min of collection.</strong> If sample cannot be received and processed in lab within this time, must be processed at the collection site.</td>
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### DAY 56 (+ 7days) POST-ACUTE PHASE

<table>
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<th>Evaluation</th>
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<th>Aliquots</th>
<th>LDMS Code</th>
<th>Special Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Serum storage for Immunologic Assays (Serum RSV AB)</td>
<td>5 mL NON or SST Blood</td>
<td>F3008</td>
<td>Save all SER in at least 3X0.5 ml aliquots</td>
<td>BLD/NON/SER OR BLD/SST/SER</td>
<td>NA</td>
</tr>
<tr>
<td>Nasal Wash for RSV Antibody</td>
<td>Nasal Wash</td>
<td>F3008</td>
<td>Store at least 2 equal (2-4 ml) aliquots, freeze at -80°C. Save all nasal wash.</td>
<td>NPW/RLS/NPW</td>
<td>Nasal Washes for RSV Antibody must be kept on wet ice until processed. NOTE: Nasal wash for antibody does not have the addition of VTM.</td>
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</table>

### SICK VISIT

<table>
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<tr>
<th>Evaluation</th>
<th>Specimen</th>
<th>CRF</th>
<th>Aliquots</th>
<th>LDMS Code</th>
<th>Special Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Nasal Wash for RSV Viral Detection and Quantification (and/or rtPCR for adventitious agents)</td>
<td>Nasal Wash</td>
<td>F3008</td>
<td>Divide into 7x1.0mL aliquots, snap freeze and store at -80°C.</td>
<td>NPW/RLS/NPW/VTM</td>
<td>Nasal Washes for RSV viral detection must be processed and snap frozen within 30 min of collection. If sample cannot be received and processed in lab within this time, must be processed at the collection site. <strong>Sick visit samples must be shipped REAL-TIME for adventitious virus assay.</strong> Include copy of F3008 with shipped samples. Please notify JHU of any changes made to LDMS or the F3008 form after the sample has been shipped.</td>
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</tbody>
</table>

### EARLY DC

<table>
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<tr>
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<th>Specimen</th>
<th>CRF</th>
<th>Aliquots</th>
<th>LDMS Code</th>
<th>Special Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Serum storage for Immunologic Assays (Serum RSV AB)</td>
<td>5 mL NON or SST Blood</td>
<td>F3008</td>
<td>Save all SER in at least 3X0.5 ml aliquots</td>
<td>BLD/NON/SER OR BLD/SST/SER</td>
<td>NA</td>
</tr>
<tr>
<td>Nasal Wash for RSV Viral Detection and Quantification (and/or rtPCR for adventitious agents)</td>
<td>Nasal Wash</td>
<td>F3008</td>
<td>Divide into 7x1.0mL aliquots, snap freeze and store at -80°C.</td>
<td>NPW/RLS/NPW/VTM</td>
<td>Nasal Washes for RSV viral detection must be processed and snap frozen within 30 min of collection. If sample cannot be received and processed in lab within this time, must be processed at the collection site.</td>
</tr>
</tbody>
</table>
### Section 4: APPENDIX 3: SCHEDULE OF EVENTS: RSV PRE-SEASON SAMPLING, SEASONAL SURVEILLANCE, AND POST-SEASON SAMPLING

#### PRE-RSV SEASON (OCT-1 to OCT-31)

<table>
<thead>
<tr>
<th>Evaluation</th>
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<th>CRF</th>
<th>Aliquots</th>
<th>LDMS Code</th>
<th>Special Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Serum storage for Immunologic Assays</td>
<td>5 mL NON or SST Blood</td>
<td>F3008</td>
<td>Save all SER in at least 3X 0.5 ml aliquots</td>
<td>BLD/NON/SER OR BLD/SST/SER</td>
<td>NA</td>
</tr>
</tbody>
</table>

#### SICK VISIT

<table>
<thead>
<tr>
<th>Evaluation</th>
<th>Specimen</th>
<th>CRF</th>
<th>Aliquots</th>
<th>LDMS Code</th>
<th>Special Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Nasal Wash for RSV Viral Detection and Quantification (and/or rtPCR for adventitious agents)</td>
<td>Nasal Wash</td>
<td>F3008</td>
<td>Divide into 7x1.0mL aliquots, snap freeze and store at -80°C.</td>
<td>NPW/RLS/NPW/VTM</td>
<td>Nasal Washes for RSV viral detection must be processed and snap frozen within 30 min of collection. If sample cannot be received and processed in lab within this time, must be processed at the collection site. Sick visit sample must be shipped REAL-TIME for adventitious virus assay. Include copy of F3008 with shipped samples. Please notify JHU of any changes made to LDMS or the F3008 form after the sample has been shipped.</td>
</tr>
</tbody>
</table>

#### POST-RSV SEASON (APRIL 1 TO APRIL 30)

<table>
<thead>
<tr>
<th>Evaluation</th>
<th>Specimen</th>
<th>CRF</th>
<th>Aliquots</th>
<th>LDMS Code</th>
<th>Special Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Serum storage for Immunologic Assays</td>
<td>5 mL NON or SST Blood</td>
<td>F3008</td>
<td>Save all SER in at least 3X 0.5 ml aliquots</td>
<td>BLD/NON/SER OR BLD/SST/SER</td>
<td>NA</td>
</tr>
</tbody>
</table>

#### EARLY DC

<table>
<thead>
<tr>
<th>Evaluation</th>
<th>Specimen</th>
<th>CRF</th>
<th>Aliquots</th>
<th>LDMS Code</th>
<th>Special Notes</th>
</tr>
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<tr>
<td>Serum storage for Immunologic Assays</td>
<td>5 mL NON or SST Blood</td>
<td>F3008</td>
<td>Save all SER in at least 3X0.5 ml aliquots</td>
<td>BLD/NON/SER OR BLD/SST/SER</td>
<td>NA</td>
</tr>
</tbody>
</table>
### Section 5: Helpful Links and Shipping Addresses

ACTG/IMPAACT Laboratory Manual, Shipping Information and other useful information:  
[http://www.hanc.info/labs/labresources/Pages/informationActgImpaactLabs.aspx](http://www.hanc.info/labs/labresources/Pages/informationActgImpaactLabs.aspx)

### SERUM Samples

- **Screening sample must be shipped real time**, M-Wed to JHU. Ship **ONE** aliquot real time on dry ice priority overnight and retain the remaining aliquots on site until requested by team.
- **For Day 56 samples**, Ship one aliquot within 2 weeks of that time point, multiple patient samples can be batched and shipped. Retain the remaining aliquots on site until requested by team.
- **EARLY DC**, Ship one aliquot within 2 weeks of that time point, multiple patient samples can be batched and shipped. Retain the remaining aliquots on site until requested by team.
- **PRE - RSV SEASON** (Oct 1-Oct 31), ship within 30 days of the end of season or by December 1
- **POST RSV SEASON** (April 1-April 30), ship within 30 days of the end of season or by June 1

### NASAL WASH for viral detection Samples

Ship **FOUR** aliquot to JHU at the end of the acute phase (Day 0-28), on dry ice priority overnight, M-Wed only. Retain 3 aliquots on site until requested by team. Multiple patient samples can be batched and shipped within 2 weeks of the time points, unless directed to ship sooner by team.

- **NASAL WASH : for adventitious virus assay.** If febrile or respiratory illness criteria are met or suspected samples must be shipped real time. Ship **FOUR** aliquot to JHU on dry ice priority overnight, M-Wed only. Retain **3** aliquots on site until requested by team

### NASAL WASH for Antibody Samples

Ship **ONE** aliquot to JHU at the end of the acute phase, and at day 56, on dry ice priority overnight, M-Wed only. Retain the **2nd** aliquots on site until requested by team. Multiple patient samples can be batched and shipped within 2 weeks of the time points, unless directed to ship sooner by team.

**SHIP TO**

**Bhavin Thumar/Kim Wainonek**  
Johns Hopkins Bloomberg School of Public Health  
Room E5402, 615 N. Wolfe Street  
Baltimore, MD 21205  
LDMS Lab code: 550  
Phone: (410) 955-7230  
Fax: (443) 287-3167  
Email: [bthumar@jhsph.edu](mailto:bthumar@jhsph.edu)

**NOTE:** Notify Bhavin Thumar ([bthumar@jhsph.edu](mailto:bthumar@jhsph.edu)) and Kim Wanionek ([kwanione@jhsph.edu](mailto:kwanione@jhsph.edu)) that a specimen is being sent. Send a copy of the F3008 specimen tracking form with your shipment. Please notify JHU of any changes made to LDMS or the F3008 form after the sample has been shipped.