### Appendix E (continued)

#### Listing of Abnormal Clinical Laboratory Results

<table>
<thead>
<tr>
<th>Subject ID</th>
<th>Vaccination Group</th>
<th>Sex</th>
<th>Age (years)</th>
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### Appendix E (continued)

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## Appendix E (continued)

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## Appendix E (continued)
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## Appendix E (continued)
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## Appendix E (continued)

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## Appendix E (continued)

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### Appendix E (continued)

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### Appendix E (continued)

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Report Date: 02JUN2020
Data Cutoff Date: 23MAY2020
### Appendix E (continued)
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### Appendix E (continued)

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Report Date: 02JUN2020
Data Cutoff Date: 25MAY2020
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**Listing of Abnormal Clinical Laboratory Results**

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### Appendix E (continued)

#### Listing of Abnormal Clinical Laboratory Results

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### Appendix E (continued)

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Report Date: 02JUN2020
Data Cutoff Date: 25MAY2020
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### Appendix E (continued)

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## Appendix E (continued)
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### Appendix E (continued)

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## Appendix E (continued)

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### Appendix E (continued)

#### Listing of Abnormal Clinical Laboratory Results

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### Appendix E (continued)

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#### Listing of Abnormal Clinical Laboratory Results

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## Appendix E (continued)
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### Appendix E (continued)
#### Listing of Abnormal Clinical Laboratory Results

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### Listing of Abnormal Clinical Laboratory Results

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### Appendix E (continued)

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## Appendix E (continued)
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### Listing of Abnormal Clinical Laboratory Results

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### Appendix E (continued)

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### Listing of Abnormal Clinical Laboratory Results

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### Appendix E (continued)

**Listing of Abnormal Clinical Laboratory Results**

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### Appendix E (continued)

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## Appendix E (continued)

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### Listing of Abnormal Clinical Laboratory Results

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Subject ID (b) (6)
### Appendix E (continued)

**Listing of Abnormal Clinical Laboratory Results**

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### Appendix E (continued)
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### Appendix E (continued)

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## Appendix E (continued)
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### Appendix E (continued)

**Listing of Abnormal Clinical Laboratory Results**

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### Appendix E (continued)

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### Appendix E (continued)

#### Listing of Abnormal Clinical Laboratory Results

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## Appendix E (continued)

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### Listing of Abnormal Clinical Laboratory Results

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### Appendix E (continued)

#### Listing of Abnormal Clinical Laboratory Results

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### Appendix E (continued)

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### Appendix E (continued)

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# Appendix E (continued)
## Listing of Abnormal Clinical Laboratory Results

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### Appendix E (continued)

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### Appendix E (continued)

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### Appendix E (continued)
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### Appendix E (continued)

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### Appendix E (continued)

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### Appendix E (continued)

**Listing of Abnormal Clinical Laboratory Results**

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### Appendix E (continued)

**Listing of Abnormal Clinical Laboratory Results**

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# Appendix E (continued)
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### Listing of Abnormal Clinical Laboratory Results

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#### Listing of Abnormal Clinical Laboratory Results

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### Appendix E (continued)

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### Appendix E (continued)

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### Appendix E (continued)

**Listing of Abnormal Clinical Laboratory Results**

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## Appendix E (continued)

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Report Date: 02JUN2020
Data Cutoff Date: 25MAY2020
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Vital Signs Listing

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--- | --- | --- | --- | --- | --- | --- | --- | --- | ---
(b) (6) | 100 mcg mRNA-1273 (18-55 years) | 15 | 14 | 37.1 | 118 | 60 | 69 | . | .
(b) (6) | 100 mcg mRNA-1273 (18-55 years) | 29 | 29 | 36.9 | 120 | 61 | 70 | . | .
(b) (6) | 100 mcg mRNA-1273 (18-55 years) | 36 | 37 | 37.1 | 117 | 56 | 68 | . | .
(b) (6) | 100 mcg mRNA-1273 (18-55 years) | 43 | 43 | 37.1 | 114 | 72 | 80 | . | .
(b) (6) | 100 mcg mRNA-1273 (18-55 years) | 57 | 58 | 37.2 | 109 | 52 | 73 | . | .
(b) (6) | 100 mcg mRNA-1273 (18-55 years) | -1 | -6 | 36.8 | 114 | 69 | 84 | 72.5 | 166.6
(b) (6) | 100 mcg mRNA-1273 (18-55 years) | 1 | 1 | 36.6 | 116 | 67 | 87 | . | .
(b) (6) | 100 mcg mRNA-1273 (18-55 years) | 8 | 7 | 36.7 | 112 | 63 | 93 | . | .
(b) (6) | 100 mcg mRNA-1273 (18-55 years) | 15 | 14 | 37 | 114 | 67 | 88 | . | .
(b) (6) | 100 mcg mRNA-1273 (18-55 years) | 29 | 29 | 36.9 | 94 | 50 | 81 | . | .
(b) (6) | 100 mcg mRNA-1273 (18-55 years) | 36 | 37 | 37.4 | 119 | 55 | 94 | . | .
(b) (6) | 100 mcg mRNA-1273 (18-55 years) | 43 | 43 | 37 | 113 | 61 | 97 | . | .
(b) (6) | 100 mcg mRNA-1273 (18-55 years) | 57 | 58 | 37.3 | 96 | 52 | 73 | . | .
(b) (6) | 25 mcg mRNA-1273 (18-55 years) | -1 | -13 | 36.5 | 110 | 70 | 63 | 76.6 | 173.7
## Appendix F (continued)
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<td>169.6</td>
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<td>100 mcg mRNA-1273 (≥71 years)</td>
<td>1</td>
<td>1</td>
<td>36.6</td>
<td>116</td>
<td>54</td>
<td>63</td>
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<tr>
<td></td>
<td>100 mcg mRNA-1273 (≥71 years)</td>
<td>8</td>
<td>8</td>
<td>36.7</td>
<td>139</td>
<td>60</td>
<td>63</td>
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<tr>
<td></td>
<td>100 mcg mRNA-1273 (≥71 years)</td>
<td>-1</td>
<td>-18</td>
<td>37.1</td>
<td>118</td>
<td>58</td>
<td>57</td>
<td>62.4</td>
<td>171</td>
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</tr>
<tr>
<td></td>
<td>100 mcg mRNA-1273 (≥71 years)</td>
<td>1</td>
<td>1</td>
<td>36.7</td>
<td>113</td>
<td>75</td>
<td>65</td>
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<td>100 mcg mRNA-1273 (≥71 years)</td>
<td>8</td>
<td>8</td>
<td>36.7</td>
<td>127</td>
<td>60</td>
<td>54 (Mild)</td>
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</tr>
<tr>
<td></td>
<td>100 mcg mRNA-1273 (≥71 years)</td>
<td>-1</td>
<td>-19</td>
<td>36.8</td>
<td>134</td>
<td>65</td>
<td>69</td>
<td>71.2</td>
<td>173.9</td>
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</table>
### Appendix F (continued)

#### Vital Signs Listing

<table>
<thead>
<tr>
<th>Subject ID</th>
<th>Vaccination Group</th>
<th>Planned Study Day</th>
<th>Actual Study Day</th>
<th>Temperature (°C)</th>
<th>Systolic Blood Pressure (mmHg)</th>
<th>Diastolic Blood Pressure (mmHg)</th>
<th>Heart Rate (beats/min)</th>
<th>Weight (kg)</th>
<th>Height (cm)</th>
</tr>
</thead>
<tbody>
<tr>
<td>(b) (6)</td>
<td>100 mcg mRNA-1273 (≥71 years)</td>
<td>1</td>
<td>1</td>
<td>36.6</td>
<td>119</td>
<td>58</td>
<td>60</td>
<td>.</td>
<td>.</td>
</tr>
<tr>
<td></td>
<td>100 mcg mRNA-1273 (≥71 years)</td>
<td>8</td>
<td>8</td>
<td>36.8</td>
<td>132</td>
<td>70</td>
<td>57</td>
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<tr>
<td></td>
<td>100 mcg mRNA-1273 (≥71 years)</td>
<td>-1</td>
<td>-17</td>
<td>37.2</td>
<td>144 (Mild)</td>
<td>83</td>
<td>78</td>
<td>80</td>
<td>165.4</td>
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<tr>
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<td>100 mcg mRNA-1273 (≥71 years)</td>
<td>1</td>
<td>1</td>
<td>37.1</td>
<td>132</td>
<td>71</td>
<td>75</td>
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</tr>
<tr>
<td></td>
<td>100 mcg mRNA-1273 (≥71 years)</td>
<td>8</td>
<td>8</td>
<td>36.9</td>
<td>142 (Mild)</td>
<td>74</td>
<td>78</td>
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### APPENDIX G1:
Listing of Protocol Deviations

<table>
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<tr>
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</tr>
</thead>
<tbody>
<tr>
<td>(b) (6)</td>
<td>250 mcg mRNA-1273 (18-55 years)</td>
<td>1</td>
<td>Too few aliquots obtained</td>
<td>Protocol procedure/assessment</td>
<td>1</td>
<td>Subject unable to comply</td>
<td>No</td>
<td>No</td>
<td>No</td>
<td>subject instructed to eat and hydrate well before clinic visit</td>
<td></td>
</tr>
<tr>
<td></td>
<td>100 mcg mRNA-1273 (18-55 years)</td>
<td>1</td>
<td>Too few aliquots obtained</td>
<td>Protocol procedure/assessment</td>
<td>1</td>
<td>Subject unable to comply</td>
<td>No</td>
<td>No</td>
<td>No</td>
<td>Not enough blood sample after multiple sticks. Subject will be advised to hydrate more.</td>
<td></td>
</tr>
<tr>
<td></td>
<td>100 mcg mRNA-1273 (18-55 years)</td>
<td>1</td>
<td>Too few aliquots obtained</td>
<td>Protocol procedure/assessment</td>
<td>1</td>
<td>Other: Poor quality PBMC layer</td>
<td>No</td>
<td>No</td>
<td>No</td>
<td>Deviation not due to human error</td>
<td></td>
</tr>
<tr>
<td></td>
<td>100 mcg mRNA-1273 (18-55 years)</td>
<td>2</td>
<td>Too few aliquots obtained</td>
<td>Protocol procedure/assessment</td>
<td>28</td>
<td>Other: Poor quality PBMC layer</td>
<td>No</td>
<td>No</td>
<td>No</td>
<td>Deviation not due to human error</td>
<td></td>
</tr>
<tr>
<td></td>
<td>100 mcg mRNA-1273 (18-55 years)</td>
<td>1</td>
<td>Too few aliquots obtained</td>
<td>Protocol procedure/assessment</td>
<td>1</td>
<td>Laboratory error</td>
<td>No</td>
<td>No</td>
<td>No</td>
<td>Rinse more CPT tubes to collect buffy coat layer</td>
<td>Suspected that the entire buffy coat wasn't collected</td>
</tr>
<tr>
<td>------------</td>
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</tr>
<tr>
<td>(b) (6)</td>
<td>100 mcg mRNA-1273 (18-55 years)</td>
<td>2</td>
<td>Too few aliquots obtained</td>
<td>Protocol procedure/assessment</td>
<td>28</td>
<td>Other: Poor quality PBMC layer</td>
<td>No</td>
<td>No</td>
<td>No</td>
<td>Deviation not due to human error</td>
<td></td>
</tr>
<tr>
<td></td>
<td>100 mcg mRNA-1273 (18-55 years)</td>
<td>3</td>
<td>Too few aliquots obtained</td>
<td>Protocol procedure/assessment</td>
<td>34</td>
<td>Other: Poor quality PBMC layer</td>
<td>No</td>
<td>No</td>
<td>No</td>
<td>Deviation not due to human error</td>
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<tr>
<td></td>
<td>100 mcg mRNA-1273 (18-55 years)</td>
<td>1</td>
<td>Too few aliquots obtained</td>
<td>Protocol procedure/assessment</td>
<td>1</td>
<td>Other: Poor quality PBMC layer</td>
<td>No</td>
<td>No</td>
<td>No</td>
<td>Deviation not due to human error</td>
<td></td>
</tr>
<tr>
<td></td>
<td>100 mcg mRNA-1273 (18-55 years)</td>
<td>2</td>
<td>Required procedure done incorrectly</td>
<td>Protocol procedure/assessment</td>
<td>55</td>
<td>Clinic error</td>
<td>No</td>
<td>No</td>
<td>No</td>
<td>Remind staff to double check the amount of blood collected.</td>
<td></td>
</tr>
<tr>
<td></td>
<td>100 mcg mRNA-1273 (18-55 years)</td>
<td>1</td>
<td>Too few aliquots obtained</td>
<td>Protocol procedure/assessment</td>
<td>1</td>
<td>Other: Poor quality PBMC layer</td>
<td>No</td>
<td>No</td>
<td>No</td>
<td>Deviation not due to human error</td>
<td></td>
</tr>
<tr>
<td></td>
<td>100 mcg mRNA-1273 (18-55 years)</td>
<td>1</td>
<td>Too few aliquots obtained</td>
<td>Protocol procedure/assessment</td>
<td>1</td>
<td>Laboratory error</td>
<td>No</td>
<td>No</td>
<td>No</td>
<td>Rinse more CPT tubes to collect buffy coat layer</td>
<td></td>
</tr>
</tbody>
</table>

Suspected that entire buffy coat wasn't collected
### Appendix G1 (continued)
#### Listing of Protocol Deviations

<table>
<thead>
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</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>250 mcg mRNA-1273 (18-55 years)</td>
<td>1</td>
<td>Too few aliquots obtained</td>
<td>Protocol procedure/assessment</td>
<td>1</td>
<td>Other: poor quality PBMC layer</td>
<td>No</td>
<td>No</td>
<td>No</td>
<td>Deviation not due to human error</td>
<td></td>
</tr>
<tr>
<td></td>
<td>25 mcg mRNA-1273 (56-70 years)</td>
<td>1</td>
<td>Too few aliquots obtained</td>
<td>Protocol procedure/assessment</td>
<td>1</td>
<td>Other: Poor quality PBMC layer</td>
<td>No</td>
<td>No</td>
<td>No</td>
<td>Deviation not due to human error</td>
<td></td>
</tr>
<tr>
<td></td>
<td>100 mcg mRNA-1273 (56-70 years)</td>
<td>1</td>
<td>Missed visit/visit not conducted</td>
<td>Follow-up visit schedule</td>
<td>2</td>
<td>Subject unable to comply</td>
<td>No</td>
<td>No</td>
<td>No</td>
<td>Explained the importance of completing study visits to the subject</td>
<td>Once contact was made with the subject, the importance of completing each study visit within the time frame was reiterated and subject responded with an understanding.</td>
</tr>
<tr>
<td></td>
<td>100 mcg mRNA-1273 (18-55 years)</td>
<td>1</td>
<td>Out of window visit</td>
<td>Follow-up visit schedule</td>
<td>46</td>
<td>Subject refusal</td>
<td>No</td>
<td>No</td>
<td>No</td>
<td>Explained the importance of attending study visits within window</td>
<td>subjects will be reminded of importance of attending study visits within window</td>
</tr>
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</table>
## Appendix G1 (continued)
### Listing of Protocol Deviations

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<tbody>
<tr>
<td></td>
<td>100 mcg mRNA-1273 (18-55 years)</td>
<td>2</td>
<td>Required procedure done incorrectly</td>
<td>Protocol procedure/assessment</td>
<td>46</td>
<td>Subject refusal</td>
<td>No</td>
<td>No</td>
<td>No</td>
<td>subject moved out of state unexpectedly</td>
<td></td>
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<tr>
<td></td>
<td>100 mcg mRNA-1273 (18-55 years)</td>
<td>3</td>
<td>Required procedure done incorrectly</td>
<td>Protocol procedure/assessment</td>
<td>55</td>
<td>Subject refusal</td>
<td>No</td>
<td>No</td>
<td>No</td>
<td>subject moved out of state unexpectedly</td>
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<tr>
<td></td>
<td>250 mcg mRNA-1273 (18-55 years)</td>
<td>1</td>
<td>Required procedure not conducted</td>
<td>Protocol procedure/assessment</td>
<td>7</td>
<td>Clinic error</td>
<td>Yes, unsolicited AE</td>
<td>No</td>
<td>No</td>
<td>Coordinator re-trained on the importance of performing required procedures</td>
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<tr>
<td></td>
<td>25 mcg mRNA-1273 (18-55 years)</td>
<td>1</td>
<td>Other: non-required lab tests performed</td>
<td>Protocol procedure/assessment</td>
<td>1</td>
<td>Laboratory error</td>
<td>No</td>
<td>No</td>
<td>N/A</td>
<td>staff instructed to review study requirements and lab form prior to submission</td>
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</table>

lab staff did not fill out requisition form properly, so complete CBC was done rather than only study required tests.
## Appendix G1 (continued)
### Listing of Protocol Deviations

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</thead>
<tbody>
<tr>
<td>(b) (6)</td>
<td>25 mcg mRNA-1273 (18-55 years)</td>
<td>1</td>
<td>Required procedure done incorrectly</td>
<td>Protocol procedure/assessment</td>
<td>-14</td>
<td>Laboratory error</td>
<td>No</td>
<td>No</td>
<td>No</td>
<td>Lab staff will prepare tubes prior to study visit and double-check tubes again post-draw</td>
<td>Incorrect tube size was used during specimen collection. As a preventative measure, lab staff will prepare blood collection tubes prior to study visits and double-check again post-draw to confirm correct tubes were used.</td>
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<tr>
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<td>100 mcg mRNA-1273 (18-55 years)</td>
<td>1</td>
<td>Other: breach of confidentiality</td>
<td>Protocol procedure/assessment</td>
<td>-4</td>
<td>Clinic error</td>
<td>No</td>
<td>No</td>
<td>N/A</td>
<td>retraining of study staff</td>
<td>subject name was included on Quest requisition form, rather than study ID.</td>
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<tr>
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<td>25 mcg mRNA-1273 (18-55 years)</td>
<td>1</td>
<td>Required procedure not conducted</td>
<td>Protocol procedure/assessment</td>
<td>8</td>
<td>Investigator/study decision</td>
<td>No</td>
<td>No</td>
<td>N/A</td>
<td>Pt. under quarantine due to exposure, required procedures will be completed at V5</td>
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</table>
### Appendix G1 (continued)
### Listing of Protocol Deviations

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</thead>
<tbody>
<tr>
<td>(b) (6)</td>
<td>25 mcg mRNA-1273</td>
<td>2</td>
<td>Other: V4 safety labs collected out of window</td>
<td>Protocol procedure/assessment</td>
<td>17</td>
<td>Subject unable to comply</td>
<td>No</td>
<td>No</td>
<td>N/A</td>
<td>Pt. unable to comply due to quarantine. V4 safety labs drawn at V5</td>
<td></td>
</tr>
<tr>
<td></td>
<td>(18-55 years)</td>
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<td></td>
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</tr>
<tr>
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<td>250 mcg mRNA-1273</td>
<td>1</td>
<td>Required procedure done incorrectly</td>
<td>Treatment administration schedule</td>
<td>28</td>
<td>Subject illness</td>
<td>No</td>
<td>No</td>
<td>No</td>
<td>Will continue to attempt to complete visits per protocol</td>
<td></td>
</tr>
<tr>
<td></td>
<td>(18-55 years)</td>
<td></td>
<td></td>
<td></td>
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</tr>
<tr>
<td></td>
<td>250 mcg mRNA-1273</td>
<td>1</td>
<td>Required procedure done incorrectly</td>
<td>Protocol procedure/assessment</td>
<td>1</td>
<td>Laboratory error</td>
<td>No</td>
<td>No</td>
<td>N/A</td>
<td>Lab staff will use a timer for visits requiring safety labs due to their shorter clot time window.</td>
<td></td>
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### APPENDIX G2:
Listing of Non-Subject Deviations

<table>
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<tr>
<th>Study Site</th>
<th>Deviation Number</th>
<th>Deviation</th>
<th>Deviation Category</th>
<th>Reason for Deviation</th>
<th>Deviation Affected Product Stability?</th>
<th>Deviation Resolution</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Emory Children's Center</td>
<td>1</td>
<td>Study product temperature excursion: EUC -80 freezer was out of range on April 17, 2020</td>
<td>Protocol procedure/assessment</td>
<td>Other:EUC -80 freezer had a malfunction.</td>
<td>Yes</td>
<td>A new -80 freezer has been purchased and in use.</td>
<td>The affected study product was immediately removed from EUC -80 freezer to EUH -80 freezer on April 17, 2020. The excursion was reported to DMID on April 18, 2020. DMID instructed to continue to use IP.</td>
</tr>
</tbody>
</table>
APPENDIX H:
Listing of Pregnancies

Table 1 – Maternal Information

No maternal information has been reported

Table 2 – Gravida and Para

No gravida and para have been reported.

Table 3 – Live Birth Outcomes

No live birth outcomes have been reported

Table 4 – Still Birth Outcomes

No maternal information has been reported

Table 5 – Spontaneous, Elective, or Therapeutic Abortion Outcomes

No spontaneous, elective, or therapeutic abortion outcomes have been reported