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<th>EUA Holder Assay Name*</th>
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<th>RNA Extraction</th>
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<td><strong>Centers for Disease Control and Prevention (CDC)</strong>&lt;br&gt;Trioplex Real-time RT-PCR Assay&lt;br&gt;March 17, 2016</td>
<td>Serum&lt;br&gt;Whole blood&lt;br&gt;Cerebrospinal fluid&lt;br&gt;Amniotic fluid&lt;br&gt;Urine&lt;br&gt;(140 – 1000 μL)</td>
<td>X X X X</td>
<td>4 h</td>
<td>Low (24)</td>
<td>First PCR assay to be granted an EUA&lt;br&gt;• Trioplex -Differentiation of ZIKV, DENV and CHIKV&lt;br&gt;• 2 different instruments for PCR&lt;br&gt;• 4 automated and 1 manual sample prep&lt;br&gt;• Limited hand-on time for sample prep. and transfer to PCR cycler; manual sample prep requires manual PCR set up as well.&lt;br&gt;• Sample Input: 1.0 mL (automated); 0.14 mL (manual)&lt;br&gt;• 5 sample types authorized: Serum, whole blood, CSF, amniotic fluid and urine</td>
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<tr>
<td><strong>Quest Diagnostics Infectious Disease, Inc.</strong>&lt;br&gt;Zika Virus RNA Qualitative Real-Time RT-PCR&lt;br&gt;April 28, 2016</td>
<td>Serum&lt;br&gt;Urine&lt;br&gt;(500 μL)</td>
<td>X X X X</td>
<td>5 h</td>
<td>Low (30)</td>
<td>Reference Laboratory&lt;br&gt;• 1 instrument for PCR&lt;br&gt;• 1 automated sample prep method&lt;br&gt;• Limited hand-on time for sample prep. and transfer to PCR cycler.&lt;br&gt;• Sample Input: 0.5 mL&lt;br&gt;• 1 sample type authorized: Serum</td>
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<td><strong>altona Diagnostics GmbH</strong>&lt;br&gt;RealStar Zika Virus RT-PCR Kit U.S.&lt;br&gt;May 13, 2016</td>
<td>Serum&lt;br&gt;EDTA Plasma&lt;br&gt;Urine&lt;br&gt;(140 – 200 μL)</td>
<td>X X X X</td>
<td>6 h</td>
<td>Low (72)</td>
<td>7 different instruments for PCR&lt;br&gt;• 2 automated and 1 manual sample prep&lt;br&gt;• Limited hand-on time for sample prep. and transfer to PCR cycler; manual sample prep requires manual PCR set up as well.&lt;br&gt;• Sample Input: 0.2 mL (automated); 0.14 mL (manual)&lt;br&gt;• 3 sample types authorized: Serum, EDTA plasma and urine</td>
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| **Hologic, Inc.**<br>Aptima Zika Virus Assay<br>June 17, 2016 | Serum<br>Plasma<br>Processed urine<br>Processed whole | ● ● | 3.5 h first results - then 5 results | High (275/ 8 hours) | Fully automated (sample to result) Panther System<br>• Sample Input: 0.7 mL<br>• 4 sample types authorized: Serum, plasma,
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<td>Viracor Eurofins Zika Virus Real-time RT-PCR Test July 19, 2016</td>
<td>blood (700 μL)</td>
<td>Man. Auto. Man. Auto.</td>
<td>every 5 min.</td>
<td></td>
<td></td>
<td>processed whole blood and processed urine</td>
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| Siemens Healthcare Diagnostics Inc. VERSANT Zika RNA 1.0 Assay (kPCR) Kit July 29, 2016 | Serum Plasma Urine (500 μL) | X X X | 5h | Low (40) |  | • Reference Laboratory  
• 1 instrument for PCR  
• 1 automated sample prep method  
• Limited hand-on time for sample prep. and transfer to PCR cycler  
• Sample Input: 0.5 mL  
• 3 sample types authorized: Plasma, Serum and urine |
| Luminex Corporation xMAP MultiFLEX Zika RNA Assay August 4, 2016 | Serum Plasma Urine (200 μL) | X X X | 4h | Low - medium (50-100) |  | • 1 instrument for PCR  
• Targets 6 distinct Zika genomic regions  
• 1 instrument for detection  
• 1 automated sample prep method  
• Limited hand-on time for sample prep. and transfer to PCR cycler  
• Sample Input: 0.2 mL  
• 3 sample types authorized: Plasma, serum and urine |
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| **Vela Diagnostics USA, Inc.** | Sentosa SA ZIKV RT-PCR Test | Serum EDTA plasma Urine (250 μL) | Man. | Auto. | ~3 h | Low (22) | - Fully automated (sample to result)  
- Sample Input: 0.25 mL  
- 3 sample types authorized: Serum, EDTA plasma and urine |
| **ARUP Laboratories** | Zika Virus Detection by RT-PCR | Serum EDTA plasma Urine (200 μL) | X | X | 6-7 h | Low (93) | - Reference Laboratory  
- 1 instrument for PCR  
- 1 automated sample prep method  
- Limited hand-on time for sample prep. and transfer to PCR cycler  
- Sample Input: 0.5 mL  
- 3 sample types authorized: Plasma, serum and urine |
| **Abbott Molecular Inc.** | Abbott RealTime Zika | Serum EDTA Plasma Whole blood Urine (500 μL) | X | X | 6.75 h | Low (94) (46 –WB) | - Automated sample prep  
- Sample prep reagents manufactured under GMP because they are also used for PMA products.  
- Instruments (m2000sp and m2000rt) readily available in many labs as they are used to run other diagnostic tests (i.e., HBV, HCV viral load testing).  
- Limited hand-on time for sample prep. and transfer to PCR cycler  
- 96 samples/run  
- Sample input: 0.5 mL volume  
- 4 sample types authorized: EDTA Plasma, serum, whole blood and urine |
| **ELITechGroup Inc.** | Molecular Diagnostics Zika ELITE MGB Kit U.S. | Serum EDTA plasma (200 μL) | Man. | Auto. | 2.5 h | Low (12) | - Fully automated (sample to result)  
- Sample Input: 0.2 mL  
- 2 sample types authorized: Serum and EDTA plasma |
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| Nanobiosym Diagnostics, Inc. Gene-RADAR Zika Virus Test March 20, 2017 | Serum (50 μL) | X | X | 2 h | Low (1) | • 1 instrument for PCR  
• Small footprint PCR instrument  
• 1 automated sample prep method  
• Sample Input: 0.05 mL  
• 1 sample type authorized: Serum |
| Thermo Fisher Scientific TaqPath Zika Virus Kit August 2, 2017 | Serum (300 μL) | X | X | 3 h | Medium - High (94) | • 1 instrument for PCR  
• 1 automated sample prep method  
• Sample Input: 0.3 mL  
• 2 sample types authorized: Serum and urine |
| Columbia University CII-ArboViroPlex rRT-PCR assay August 11, 2017 | Serum (250 μL) | X | X | 6 h | Low (88) | • Quadruplex -Differentiation between ZIKV, DENV WNV and CHIKV  
• 1 instrument for PCR  
• 1 automated sample prep method  
• Sample Input: 0.25 mL  
• 2 sample types authorized: Serum and urine |

*Listed in order of initial EUA issuance, information current as of May 1, 2018;  
$Specimen volume dependent on the extraction method used  
^Throughput parameters used: High = >250/8-10h day; Medium = 100 to 250/8-10h day; Low = < 100/8-10h day  
• = Same instrument for extraction and amplification reaction set-up.