Reporting Title: Zika Virus Real-time RT-PCR
Test Definition: 4800
Testing Location: Lee’s Summit, MO
Reporting Location: Melville, NY

Description:
Zika infection during pregnancy can cause a serious birth defect called microcephaly that is a sign of incomplete brain development. Microcephaly is a condition where a baby’s head is much smaller than expected. During pregnancy, a baby’s head grows because the baby’s brain grows. Microcephaly can occur because a baby’s brain has not developed properly during pregnancy or has stopped growing after birth, which results in a smaller head size. Microcephaly can be an isolated condition, meaning that it can occur with no other major birth defects, or it can occur in combination with other major birth defects. Doctors have also found other problems in pregnancies and among fetuses and infants infected with Zika virus before birth.

Zika Virus Real-time RT-PCR test is a real-time RT-PCR test intended for the qualitative detection of RNA from Zika virus in human plasma, serum or urine (collected alongside a patient matched serum or plasma specimen). Specimens are collected from individuals meeting Zika virus clinical criteria (e.g., clinical signs and symptoms associated with Zika virus infection) and/or Zika virus epidemiological criteria (e.g., history of residence in or travel to a geographic region with active Zika transmission at the time of travel, or other epidemiologic criteria for which Zika virus testing may be indicated). Health care providers are strongly encouraged to collect serum/plasma specimens alongside other specimen types to provide additional opportunities for diagnosing Zika virus infection in cases when PCR tests are negative.

Analytical Method(s):
Extraction of Zika virus nucleic acid from specimen, followed by combined reverse transcription of viral RNA and PCR amplification using real-time, RT-PCR methods. An internal control is added to ensure that extraction was performed correctly and that the RT-PCR reaction was not inhibited. This test has not been cleared or approved for diagnostic use by the U.S. Food and Drug Administration. This test has been authorized by FDA under an EUA for use by authorized laboratories. This test has been authorized only for the detection of RNA from Zika virus and diagnosis of Zika virus infection, not for any other viruses or pathogens. This test is only authorized for the duration of the declaration that circumstances exist justifying the authorization of the emergency use of in vitro diagnostic tests for detection of Zika virus and/or diagnosis of Zika virus infection under section 564(b)(1) of the Act, 21 U.S.C. § 360bbb-3(b)(1), unless the authorization is terminated or revoked sooner. The test is performed by Eurofins Viracor, Inc. 1001 NW Technology Dr. Lee’s Summit, MO 64086.

Patient Preparation:
Counsel patient on their risk of Zika infection.

Specimen Requirements:
Specimen Type: Serum or Urine (Collection of Serum and Urine specimens is recommended)

Container/Tube:
Serum: Red-top Vacutainer® tube or Serum Separator Tube (Red/Grey or Gold top SST).
Urine: Yellow-top Vacutainer® Plus urinalysis tube

Specimen Volume:
Serum: 1.0 ml of spun serum or 5 ml of unspun whole blood.
Urine: 1.0 ml minimum

Specimen Stability: Serum samples are stable at ambient temperature for 6 days.

Specimen Rejection Criteria: hemolysis, lipemia, incorrect tube type, insufficient volume

Additional Information:

CPT Code: 87798

Reference Values:
An Interpretive Report will be provided.

Supplemental Report:
No

Testing Algorithm:
For up to date testing algorithms see: https://www.cdc.gov/zika/hc-providers/testing-guidance.html

Consents/Authorizations:
1. A Zika Virus Real-time RT-PCR Test: Patient Consent Form is available.
2. Patient signature on requisition form is required.

Disclaimer:
The Zika Virus Real-time RT-PCR test is a laboratory test designed to detect Zika virus. The U.S. Food and Drug Administration (FDA) has not cleared or approved this test. No FDA-cleared or approved tests exist that can tell whether you have Zika virus infection. However, FDA has authorized the use of this test under an Emergency Use Authorization (EUA). Like all other EUA authorizations, this test has been authorized by FDA under an EUA for use by authorized laboratories. This test has been authorized only for the detection of RNA from Zika virus and diagnosis of Zika virus infection, not for any other viruses or pathogens. This test is only authorized for the duration of the declaration that circumstances exist justifying the authorization of the emergency use of in vitro diagnostic tests for detection of Zika virus and/or diagnosis of Zika virus infection under section 564(b)(1) of the Act, 21 U.S. C. § 360bbb-3(b)(1), unless the authorization is terminated or revoked sooner. Information regarding the Zika virus is changing regularly, the information in this brochure was accurate as of the date of publication. For the most current Zika news and updates, please visit www.cdc.gov/zika.
Test Requisition Instructions

Complete Physician Information and Patient Information sections. Be sure to check off the specific Test Request.

Specimen Labels – Preprinted with the requisition number. Please enter the patients last and first names EXACTLY as they appear on the requisition form. Affix the label to the patient specimen. Please complete the date and time collected fields.

Billing Information – Provide a photocopy of the front and back of insurance card or print the information in the required fields. Please provide credit card information to cover tests ordered requiring additional charges.
## Test Requisition Form

### Physician Information

<table>
<thead>
<tr>
<th>Name (Last, First, MI)</th>
<th>Address</th>
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<tr>
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<th>Zip</th>
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<tr>
<th>Phone</th>
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### Patient Information

<table>
<thead>
<tr>
<th>Name (Last, First, MI)</th>
<th>Sex #</th>
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<tbody>
<tr>
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<table>
<thead>
<tr>
<th>Male</th>
<th>Female</th>
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<tbody>
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</tbody>
</table>

### Specimen Labeling

- **Urine Cup**
- **Urine Vacutainer Tube**
- **Serum Separator Tube**
- **Serum Transfer Tube**

Enter patient's name on specimen identification label exactly as it appears on the test requisition form to the left. Two forms of patient ID must appear on the test requisition form and both specimens.

### Client Accession Number

<table>
<thead>
<tr>
<th>NTD Labs Use Only</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Specimens Received</th>
<th>Urine</th>
<th>Serum</th>
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<tbody>
<tr>
<td></td>
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### Test Request (Please check all that apply)

<table>
<thead>
<tr>
<th>Specimen Type(s)</th>
<th>Test Request</th>
</tr>
</thead>
<tbody>
<tr>
<td>Urine</td>
<td>Zika Virus RT-PCR (Urine and/or Serum)</td>
</tr>
<tr>
<td>Serum</td>
<td>Zika Virus RT-PCR (Urine and/or Serum)</td>
</tr>
</tbody>
</table>

### Current Zika virus testing algorithms available at:


### Patient Billing Information

<table>
<thead>
<tr>
<th>Name (as appears on credit card)</th>
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<th>Address 2</th>
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<tbody>
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<table>
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</thead>
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</tbody>
</table>

This shall confirm that the undersigned has agreed to pay the discounted amount listed above using the credit card information, check or money order provided and that such payment shall be deemed in full and the undersigned shall not be charged or responsible for any amounts for the procedure, except as provided below. The undersigned confirms that he/she is not enrolled in any state Medicaid program, is not currently applying for Medicaid benefits, and is not entitled to any state Medicaid benefits or to any Medicare Managed Care coverage. The undersigned further agrees that because most payers at the present time do not or will not reimburse for Zika virus testing, and because before is therefore being tested as unsuitable for these purposes and being given the discounted fee identified above, he/she represents and agrees that neither he/she nor any one on his/her behalf will submit a claim for reimbursement for such Zika virus testing to any insurer, company, or other third-party payer, including but not limited to any federal and/or state reimbursement programs, auto/worker's compensation programs, commercial insurance, self-insured programs, ASRs, PAs, etc. The undersigned agents that should he/she submit a claim for reimbursement to any such insurance company or third party payer, NTD Labs will point paying for the test to the full list price and the undersigned will be responsible for any additional amounts required to collect payment in full as stated from either his/her insurance company or other third-party payer. The undersigned has been provided information about Zika virus testing and consents to have the specimen he/she has supplied tested for the Zika virus.

<table>
<thead>
<tr>
<th>Patient Signature (required)</th>
<th>Signature of Credit Card Holder (if different than patient)</th>
<th>Date</th>
</tr>
</thead>
<tbody>
<tr>
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</tbody>
</table>

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Specimen Collection Instructions

Zika Virus Specimen Collection

Test Name: Zika Virus Rt-PCR (Qual)  Test Name: Zika Virus IgM
Test Code: 4800  Test Code: 30294

Urine collection procedure:
1. Peel back sticker
   - If patient’s urine sample is collected, peel back protective sticker to expose rubber-covered cannula
2. Insert urine tube
   - Push urine tube (yellow top) into integrated transfer port
   - Hold in position until flow stops
3. Cover and label
   - Place protective sticker back over the integrated transfer port
   - Affix the requisition label to the tube, and write in patient’s first and last name exactly as they appear on the requisition
4. Dispose and transport
   - Remove lid from cup and dispose in a sharps collector
   - Dispose of urine according to your policy
   - Dispose of collection cup as a biohazard
   - Immediately transport labeled urine tube to the laboratory

Serum collection procedure:

Invert 5 times
- Gently invert 5 times to mix clot activator with blood
Clot 30 minutes
- Allow blood to clot for a minimum of 30 minutes, but no longer than 2 hours, in a vertical position
- Observe a dense clot
Spin 10 minutes
- Centrifuge at full speed (between 1100 and 1300g) for 10 minutes for swing-out units or for 15 minutes for fixed-angle units (balance tube in centrifuge)
- Barrier will form, separating serum specimen from clot
Transfer
- Transfer serum to the plastic transfer tube
- Affix the requisition label to the transfer tube
- Immediately transport labeled transfer tube to laboratory on ice (see reverse side)
Zika Virus Specimen Packaging and Shipping

Specimens must be immediately refrigerated and received at NTD Labs within 48 hours of collection. Transit time may not exceed 24 hours.

**Specimen packaging:**

1. Place the spun serum and/or urine vacuainer tube in absorbent pouch inside biohazard bag
2. Place completed requisition in outside pouch of biohazard bag

**Specimen rejection criteria:**
- Grossly hemolyzed
- No Pos-ID (full name + requisition # or date of birth)
- No test requisition included with sample
- Not received next day
- Not shipped with ice packs

**Specimen shipping:**

1. Place biohazard bag containing specimens inside flexible ice pouch
2. Place flexible ice pouch at bottom of shipping box
3. Add all 3 Cryo-Gel™ refrigerant packs on top of the flexible ice pouch with sample(s)
4. Place cooler lid on top, and seal shipping box
5. Call FedEx for same-day pickup
6. Retain FedEx ticket with tracking number for your records

**Shipping:**

Ship Monday through Friday, labeled for FedEx Priority Overnight with Saturday delivery. Specimens may not be in transit more than 24 hours.

**Ship specimen to:**

NTD Labs
80 Ruland Road, Suite 1
Mehville, NY 11747

*If FedEx is missed on day of collection, keep sample(s) refrigerated and send the following day with FRESH ice packs.*
Specimen Collection Instructions

See also Blood Specimen Collection from Venipuncture Instruction Manual.

EMR Ask at Order Entry (AOE) Questions: None

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<td>80824-6</td>
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<td></td>
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</table>
Patient Consent Form

Zika Virus Real-time RT-PCR Test: Patient Consent Form

Dear Patient:

You are being given this Fact Sheet because your blood and/or urine will be tested for evidence of Zika virus infection. This testing is done because you have symptoms of Zika virus infection and because you live in or have traveled recently to a place where Zika virus infection is known to occur, and/or because you have another possible exposure to Zika virus (e.g., sexual transmission). The test used on your specimen(s) is called the Zika Virus Real-time RT-PCR test, which is a laboratory test designed to help detect Zika virus infection in humans. This Fact Sheet contains information to help you understand the risks and benefits of using the Zika Virus Real-time RT-PCR test. You may want to discuss with your health care provider the benefits and risks described in this Fact Sheet and any additional questions you may have.

What is Zika virus infection?

Zika virus infection is caused by the Zika virus which is most often spread to people through mosquito bites. A woman infected with Zika virus during pregnancy can pass the virus to her developing baby. Zika virus can also be passed by an infected man to his partner during sex. Since 2015, a large number of Zika virus cases have been reported in many South and Central American and Caribbean countries. Most people who are infected with Zika virus do not have any symptoms. Those that do, usually have mild illness with symptoms that may include fever, joint pain, rash, or redness of the eyes. These symptoms often resolve on their own within a week. Infection with Zika virus during pregnancy can cause microcephaly (where the baby’s head is smaller than expected, a sign of incomplete brain development) and other severe brain defects in fetuses and infants. However, detection of Zika virus infection in the mother does not mean there is definite harm to the developing baby. Some women who had Zika virus infection during pregnancy have delivered apparently healthy babies. Women who are infected with Zika virus while pregnant should be monitored more closely by their health care providers throughout their pregnancy. There have also been reports of a possible link between Zika virus infection and an illness that can cause temporary paralysis (Guillain-Barré syndrome).

What is the Zika Virus Real-time RT-PCR test?

The Zika Virus Real-time RT-PCR test is a laboratory test designed to detect Zika virus. The U.S. Food and Drug Administration (FDA) has not cleared or approved this test. No FDA-cleared or approved tests exist that can tell whether you have Zika virus infection. However, FDA has authorized the use of this test under an Emergency Use Authorization (EUA).

Why is my sample being tested using the Zika Virus Real-time RT-PCR test?

When using the test, your blood and/or urine sample(s) are tested because you have symptoms of Zika virus infection and because you live in or have traveled recently to a place where Zika virus infection is known to occur, and/or because you have another possible exposure to Zika virus (e.g., sexual transmission). The sample(s) collected from you will be tested using the Zika Virus Real-time RT-PCR test to help find out whether you may be infected with Zika virus. The test results, along with other information, could help your health care provider make decisions about how to take care of you and better monitor your pregnancy.

What are the known and potential risks and benefits of the Zika Virus Real-time RT-PCR test?

Besides possible discomfort and other complications that can happen when your specimen is collected, there is a risk that the test result will be incorrect (see next paragraphs for more information). The benefit of having this test is that the results of this test, along with other information, can help your health care provider make decisions about how to take care of you and develop your baby.

If this test is positive for Zika virus, does it mean that I have a Zika virus infection?

If you have a positive test result, it is very likely that you have a Zika virus infection. There is a very small chance that this test can give a positive result that is wrong; this is called a “false positive” result. If your result from this test is positive, your health care provider or health department will work with you to help you understand the steps you should take to care for yourself. They will also work closely with you to monitor the health and development of your baby. Information about steps to take if you are diagnosed with Zika virus infection is available at http://www.cdc.gov/zika/index.html.

If this test is positive for Zika virus, does it mean that my baby will have a birth defect?

No, not necessarily. While evidence shows that Zika virus infection during pregnancy is a cause of birth defects and other poor pregnancy outcomes, not all Zika virus infections result in these pregnancy problems. At this time, we do not know how often babies will have microcephaly or other problems if a woman is infected with Zika virus while she is pregnant. A positive test result for Zika virus infection during pregnancy signals to your doctor or other health care provider to watch your pregnancy more closely, meaning he or she might do more ultrasounds or other tests to check the growth and development of your fetus and check for any signs of Zika virus infection.

NTD:0816
Zika Virus Real-time RT-PCR Test: Patient Consent Form

If this test is negative for Zika virus, does it mean that I do not have a Zika virus infection?
A negative test result means that Zika virus was not found in your sample. A negative result for a sample collected less than a week after the start of illness usually means that Zika virus did not cause your recent illness. It is possible for this test to give a negative result that is incorrect (false negative) in some people with a Zika virus infection. Most people with Zika virus infection have virus in their blood for up to a week following the start of illness. The length of time an infected person will have virus in his or her urine is not clearly known at this point. A negative result that is incorrect can happen if your body fights a Zika virus infection faster than most other people do. It can also happen if your illness/symptoms were very mild and started earlier than the date you first noticed them. In these cases, the virus may already be gone from your system before the sample was taken for testing. If your Zika result from the Zika Virus Real-time RT-PCR test is negative, you should ask your health care provider or health department if additional testing may be needed. It is important that you work with your health care provider or health department to help you understand the next steps you should take. Your health care provider will work with you to continue to monitor your health and the health of your baby.

What is an Emergency Use Authorization (EUA)?
An EUA is a tool that FDA can use to allow the use of certain medical products for certain emergencies based on scientific data. The U.S. Secretary of Health and Human Services (HHS) has declared that circumstances exist to allow the emergency use of authorized diagnostic tests for Zika virus infection, such as the Zika Virus Real-time RT-PCR test, under an EUA. At this time, there are no FDA approved/cleared alternative tests available that detect Zika virus. FDA has authorized the emergency use of the Zika Virus Real-time RT-PCR test to test for the presence of Zika virus in blood and urine specimens. Use of this test is authorized only for the duration of the threat of the emergency, unless it is terminated or revoked by FDA sooner.

How can I learn more?
Information about Zika virus is available at the CDC website: http://www.cdc.gov/zika/index.html. Any significant new findings that negatively impact the performance of the test and that are observed during the course of the emergency use of the Zika Virus Real-time RT-PCR test will be made available at the Viraco-IBT Laboratories, Inc. website: www.viracoibt.com/zika. Please also contact your health care provider if you have any questions.

Patient Consent

By signing this form, I, the patient having the testing performed, acknowledge that I have been offered the opportunity to ask questions and discuss with my healthcare provider the benefits, risks, and limitations of the test to be performed; I have discussed with the healthcare provider ordering this test the reliability of positive or negative test results and the level of certainty that a positive test result for a given disease or condition serves as a predictor of that disease or condition; I have received and read the Fact Sheet for Pregnant Women Understanding Results from the Zika Virus Real-time RT-PCR Test sheet in its entirety and realize I may retain a copy for my records; I consent to having this test performed and I will discuss the results and appropriate medical management with my healthcare provider; I have read and agree to the Financial Responsibility Statement.

☐ I agree to testing:

Patient Signature: ___________________________ Date: ____________

☐ I decline testing:

Patient Signature: ___________________________ Date: ____________

This Patient Informed Consent Form (the "Consent") provided by NTD Labs solely as a courtesy to physicians and their patients as a starting point, which may or may not be used in your sole discretion, for addressing the issue of informed consent. The actual informed consent form that you may need to use may differ in light of specific additional and/or different requirements that may be mandated on a country or state-by-state or other legal basis. The Consent is provided as is without any representation or warranty as to its applicability, completeness, accuracy or compliance with state and/or federal legal requirements or otherwise. By providing this Consent, NTD Labs is not, and should not be considered as, providing any legal or other advice with respect to informed consent or informed consent forms.

NTD-0816
Example Report

NTD LABS
80 Rutland Road • Melville, NY 11747 • (631) 425-8800 • Fax (631) 425-0881 • Email: ntdlabs@perkinelmer.com

Zika Virus Testing

Patient Name: ZIKA, TEST
Specimen Type: URINE+PLASMA
Patient ID #: 8500103
Date of Birth: 06/22/1972
Date Collected: 05/25/2016
Date Received: 05/27/2016
Date Reported: 6/14/2016

Physician: 24328 Tel: 06000000000
OB SPECIALISTS
100 ANYWHERE ST
SOMETHERE, US 99999

Zika Virus Testing was performed at:
Viracor-IBT Laboratories - 1001 NW Technology Dr., Lee's Summit, MO | CLIA# 26D-0983643

See Attached Report

The information contained in this fax transmission is intended only for the user or the individual or entity to whom or to which it is addressed, and may contain information that is privileged, confidential and exempt from disclosure under applicable law. If the reader of this communication is not the intended recipient, or the employee or agent responsible for delivering this communication to the intended recipient, you are hereby notified that any dissemination, distribution, copying or disclosure of this communication is strictly prohibited. If you have received this transmission in error please notify the sender immediately by telephone and fax and destroy any copies. If this communication has been received electronically, delete the original communication and any attachment from any computer, server or other electronic recording or storage device or medium. No confidentiality or privilege is waived or lost by any mis transmission. Please notify NTD Laboratories if you are receiving patient information or other confidential information and your fax machine is not in a secure location. Please notify if there is an alternative fax number we may use.

Jonathan B. Carmichael, Ph.D,
Laboratory Director

Terrence W. Hallahan, Ph.D,
Laboratory Director

*8500103*
Fax: 9999999999
LABORATORY REPORT

PATIENT NAME: REPORT, SAMPLE IA W
SEX: M
DOB: 01/01/1985
AGE: 31y
VIRACOR-IBT PATIENT ID: 5324500
PHYSICIAN: UnDefined...
RECEIVED: 06/14/2016 15:21
REPORT DELIVERED: 06/14/2016 15:36

CLIENT MRN: 64727421
CLIENT: Viracor-IBT Validation
1234 1st Street
Suite B
Anywhere, Mo 11223

RESULTS

Zika Virus RT-PCR (plasma) 4800
Client Accession ID:
Performed at: Viracor-IBT Laboratories - 1001 NW Technology Dr., Lee's Summit, MO | CLI# 2SD-0983643

TEST
Zika RT-PCR

RESULT
Detected

Expected Value: Not Detected
Specimens with a "Not Detected" PCR result that are obtained from pregnant women should be followed up with zika serology testing to further evaluate the zika status of the patient.

This test was developed and its performance characteristics determined by Viracor-IBT Laboratories. It has not been cleared or approved by the U.S. Food and Drug Administration. Results should be used in conjunction with clinical findings, and should not form the sole basis for a diagnosis or treatment decision.

PCR tests are performed pursuant to a license agreement with Roche Molecular Systems.

Zika Virus RT-PCR (urine) 4800
Client Accession ID:
Performed at: Viracor-IBT Laboratories - 1001 NW Technology Dr., Lee's Summit, MO | CLI# 2SD-0983643

TEST
Zika RT-PCR

RESULT
Detected

Expected Value: Not Detected
Specimens with a "Not Detected" PCR result that are obtained from pregnant women should be followed up with zika serology testing to further evaluate the zika status of the patient.

This test was developed and its performance characteristics determined by Viracor-IBT Laboratories. It has not been cleared or approved by the U.S. Food and Drug Administration. Results should be used in conjunction with clinical findings, and should not form the sole basis for a diagnosis or treatment decision.

PCR tests are performed pursuant to a license agreement with Roche Molecular Systems.

For questions or technical issues, please contact us at 1(800)305-5198. You may also visit our website at www.ViracorIBT.com.

Viracor-IBT Laboratories Headquarters: 1001 NW Technology Dr., Lee's Summit, MO 64064
1(800)305-5198
Page: 1 of 1
REPORT, SAMPLE IA W, OrderId:1606142413

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During the actual use of this form, cover page need not be printed.
Detect Zika Virus with Testing from NTD

Zika Virus Testing from NTD Labs: Zika RT-PCR and Zika IgM

Eurofins NTD and Viracor have partnered to provide custom Zika virus testing to meet your patients’ Zika virus screening needs.

Zika Virus Real-time RT-PCR is intended for the qualitative detection of RNA from Zika virus in human plasma, serum or urine. Healthcare providers are strongly encouraged to collect serum specimens alongside other specimen types to provide additional opportunities for diagnosing Zika virus infection in cases when PCR tests are negative. Option to refer to PCR testing is available.

ZIKV Detect™ IgM Capture ELISA is intended for the presumptive detection of Zika virus IgM antibodies in serum samples. Both tests are intended for individuals meeting Zika virus clinical criteria and/or Zika virus epidemiological criteria. No FDA-cleared or approved tests exist for Zika virus infection. However, the FDA has authorized the use of these tests under an Emergency Use Authorization (EUA). Option to refer to PCR testing is available.

Current CDC Recommendations for Testing

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<thead>
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<th>Days Since Exposure or Symptom Onset</th>
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<th>Symptomatic</th>
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<tbody>
<tr>
<td>&lt;14 days</td>
<td>- Zika Virus RT-PCR (urine + serum)</td>
<td>- Zika Virus RT-PCR (urine + serum)</td>
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<tr>
<td></td>
<td>- Reflex negative RT-PCR results w/Zika IgM (serum) drawn &gt;14 days</td>
<td>- Reflex negative RT-PCR results to Zika IgM (serum)</td>
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<tr>
<td>&gt;14 days</td>
<td>- Zika IgM (serum)</td>
<td>- Zika IgM (serum)</td>
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<tr>
<td></td>
<td>- Reflex positive IgM results w/RT-PCR (serum + urine); reflex negative RT-PCR results w/PRNT</td>
<td>- Reflex positive IgM results to RT-PCR (serum + urine)</td>
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Current Zika virus testing algorithm available at www.cdc.gov/zikavirus/lab-guidance.html.

Additional Criteria and Testing Strategies for Pregnant Women

- If a positive anti-Zika IgM result is obtained, testing by Zika RT-PCR, on all appropriate specimen types available, should be performed.
- If the Zika RT-PCR test results are negative, testing should proceed to PRNT to test for the presence of neutralizing anti-Zika antibodies.
  - When indicated, Viracor’s Notifiable Disease Reporting (NSR) group will contact the state health department where the patient is from and arrange for the confirmatory PRNT testing.
- Anti-dengue IgM testing is recommended for symptomatic pregnant women.
Sample Requirements

Paired samples (serum and urine) are the preferred sample type for Zika RT-PCR. While Zika RNA is typically detected within the first 2 weeks following symptom onset or possible exposure, Zika RNA may be detected for prolonged periods in some pregnant women. Serum is the only sample type currently authorized for Zika IgM.

Please refer to NTD's Zika Specimen Collection Guide for details on sample collection and shipping.

Why Use NTD for Your Zika Testing?

Ease of use

- Fast turnaround time (3 days from sample receipt at NTD)
- Sample collection and shipping supplies provided, with clear and simple instructions
- The NTD Client Services team you have come to trust

Quality and experience

- For more than 40 years, NTD Labs has been an innovative leader in prenatal screening, providing accurate and timely information to healthcare providers and expectant parents.
- Vitcor has more than 30 years of specialized expertise in infectious disease, immunology and allergy testing for immunocompromised and critical patients.

Multiple sample types and test options

- Blood (plasma/serum) and urine
- Zika virus RT-PCR and IgM, with reflex test options to meet CDC/ACOG recommendations

Billing information

- Cash payment or client bill only
- Reduced pricing available with up-front payment
- Credit card, check or money order accepted

*Not available for patients with or applying for Medicaid/Managed Medicaid.

For more information about NTD’s Zika virus testing, or to order test kits, please contact your local Genetics Account Executive or call our Client Services department at 1-888-NTD-LABS (683-5227).

NTD Eurofins Clinical Diagnostics

80 Rutland Road, Suite 1, Melville, NY 11747
www.ntdlabs.com 1-888-NTD-LABS (683-5227)
Dear Patient,

You are being given this Fact Sheet because your blood or urine has been tested for evidence of Zika virus infection. This testing was done because you have symptoms of Zika virus infection and because you live in or have traveled recently to a place where Zika virus infection is known to occur, and/or because you have another possible exposure to Zika virus (e.g., sexual transmission). The test used on your specimen(s) is called the Zika Virus Real-time RT-PCR test, which is a laboratory test designed to help detect Zika virus infection in humans.

This Fact Sheet contains information to help you understand the risks and benefits of using the Zika Virus Real-time RT-PCR test. You may want to discuss with your health care provider the benefits and risks described in this Fact Sheet and any additional questions you may have.

What is Zika virus infection?

Zika virus infection is caused by the Zika virus, which is most often spread to people through mosquito bites. A woman infected with Zika virus during pregnancy can pass the virus to her developing baby. Zika virus can also be passed by an infected man to his partner during sex. Since 2015, a large number of Zika virus cases have been reported in many South and Central American and Caribbean countries.

Most people who are infected with Zika virus do not have any symptoms. Those who do usually have mild illness with symptoms that may include fever, joint pain, rash, or redness of the eyes. These symptoms often resolve on their own within a week.

Infection with Zika virus during pregnancy can cause microcephaly (where the baby’s head is smaller than expected, a sign of incomplete brain development) and other severe brain defects in fetuses and infants. However, detection of Zika virus infection in the mother does not mean there is definite harm to the developing baby. Some women who have had Zika virus infection during pregnancy have delivered apparently healthy babies. Women who are infected with Zika virus while pregnant should be monitored more closely by their health care providers throughout their pregnancy.

There have also been reports of a possible link between Zika virus infection and an illness that can cause temporary paralysis (Guillain-Barré syndrome).
What is the Zika Virus Real-time RT-PCR test?

The Zika Virus Real-time RT-PCR test is a laboratory test designed to detect Zika virus. The U.S. Food and Drug Administration (FDA) has not cleared or approved this test. No FDA-cleared or approved tests exist that can tell whether you have Zika virus infection. However, the FDA has authorized the use of this test under an Emergency Use Authorization (EUA).

Why was my sample tested using the Zika Virus Real-time RT-PCR test?

Your blood or urine sample was tested because you have symptoms of Zika virus infection and because you live in or have traveled recently to a place where Zika virus infection is known to occur, and/or because you have another possible exposure to Zika virus (e.g., sexual transmission). The sample collected from you was tested using the Zika Virus Real-time RT-PCR test to help find out whether you may be infected with Zika virus. The test results, along with other information, could help your health care provider make decisions about how to take care of you and better monitor your pregnancy.

What are the known and potential risks and benefits of the Zika Virus Real-time RT-PCR test?

Besides possible discomfort and other complications that can happen when your specimen is collected, there is a risk that the test result will be incorrect (see next paragraphs for more information). The benefit of having this test is that the results of this test, along with other information, can help your health care provider make decisions about how to take care of you and your developing baby.

If you live in an area with Zika, the CDC (Centers for Disease Control and Prevention) recommends testing when you start prenatal care and again during your second trimester.*

*Available at www.cdc.gov/ds/paz/medtesttool.html
If this test is positive for Zika virus, does it mean that I have a Zika virus infection?

If you have a positive test result, it is very likely that you have a Zika virus infection. There is a very small chance that this test can give a positive result that is wrong, this is called a false-positive result. If your result from this test is positive, your health care provider or health department will work with you to help you understand the steps you should take to care for yourself. They will also work closely with you to monitor the health and development of your baby. Information about steps to take if you are diagnosed with Zika virus infection is available at http://www.cdc.gov/zika/index.html.

If this test is positive for Zika virus, does it mean that my baby will have a birth defect?

No, not necessarily. While evidence shows that Zika virus infection during pregnancy is a cause of birth defects and other poor pregnancy outcomes, not all Zika virus infections result in these pregnancy problems. At this time, we do not know how often babies will have microcephaly or other problems if a woman is infected with Zika virus while she is pregnant. A positive test result for Zika virus infection during pregnancy signals to your doctor or other health care provider to watch your pregnancy more closely, and they might do more ultrasounds or other tests to check the growth and development of your fetus and check for any signs of Zika virus infection.

If this test is negative for Zika virus, does it mean that I do not have a Zika virus infection?

A negative test result means that Zika virus was not found in your sample. A negative result for a sample collected less than a week after the start of illness usually means that Zika virus did not cause your recent illness.
It is possible for this test to give a negative result that is incorrect (false negative) in some people with a Zika virus infection. Most people with Zika virus infection have the virus in their blood for up to a week following the start of illness. The length of time an infected person will have the virus in his or her urine is not clearly known at this point. A negative result that is incorrect can happen if your body fights a Zika virus infection faster than most other people's bodies do. It can also happen if your illness/symptoms were very mild and started earlier than the date you first noticed them. In these cases, the virus may have already been gone from your system before the sample was taken for testing.

If your Zika result from the Zika Virus Real-time RT-PCR test is negative, you should ask your health care provider or health department if additional testing may be needed. It is important that you work with your health care provider or health department to help you understand the next steps you should take. Your health care provider will work with you to continue to monitor your health and the health of your baby.

What is an Emergency Use Authorization (EUA)?

An EUA is a tool that FDA can use to allow the application of certain medical products for certain emergencies, based on scientific data. The U.S. Secretary of Health and Human Services (HHS) has declared that circumstances exist to allow the emergency use of authorized diagnostic tests for Zika virus infection, such as the Zika Virus Real-time RT-PCR test, under an EUA.

At this time, there are no FDA-approved/cleared alternative tests available that detect Zika virus. The FDA has authorized the emergency use of the Zika Virus Real-time RT-PCR test to screen for the presence of Zika virus in blood and urine specimens. Use of this test is authorized only for the duration of the threat of the emergency, unless it is terminated or revoked by the FDA sooner.
How can I learn more?

Information about Zika virus is available at the CDC website: [http://www.cdc.gov/zika/index.html](http://www.cdc.gov/zika/index.html). Any significant new findings that negatively impact the performance of the test and that are observed during the course of the emergency use of the Zika Virus Real-time RT-PCR test will be made available at the Viracor-IBT Laboratories, Inc., website: [www.viracoribt.com/zika](http://www.viracoribt.com/zika). Please also speak with your healthcare provider if you have any questions.

About NTD Labs

A Eurofins company, NTD Labs has been a leader in prenatal testing for over four decades. We provide risk assessment services that help healthcare professionals and patients make more-informed medical decisions. Universities, medical centers, hospitals, laboratories, and physicians around the world trust NTD Labs for timely results and excellent accuracy.

Information regarding the Zika virus is changing regularly. The information in this brochure was accurate as of the date of publication. For the most current Zika news and updates, please visit [www.cdc.gov/zika](http://www.cdc.gov/zika).