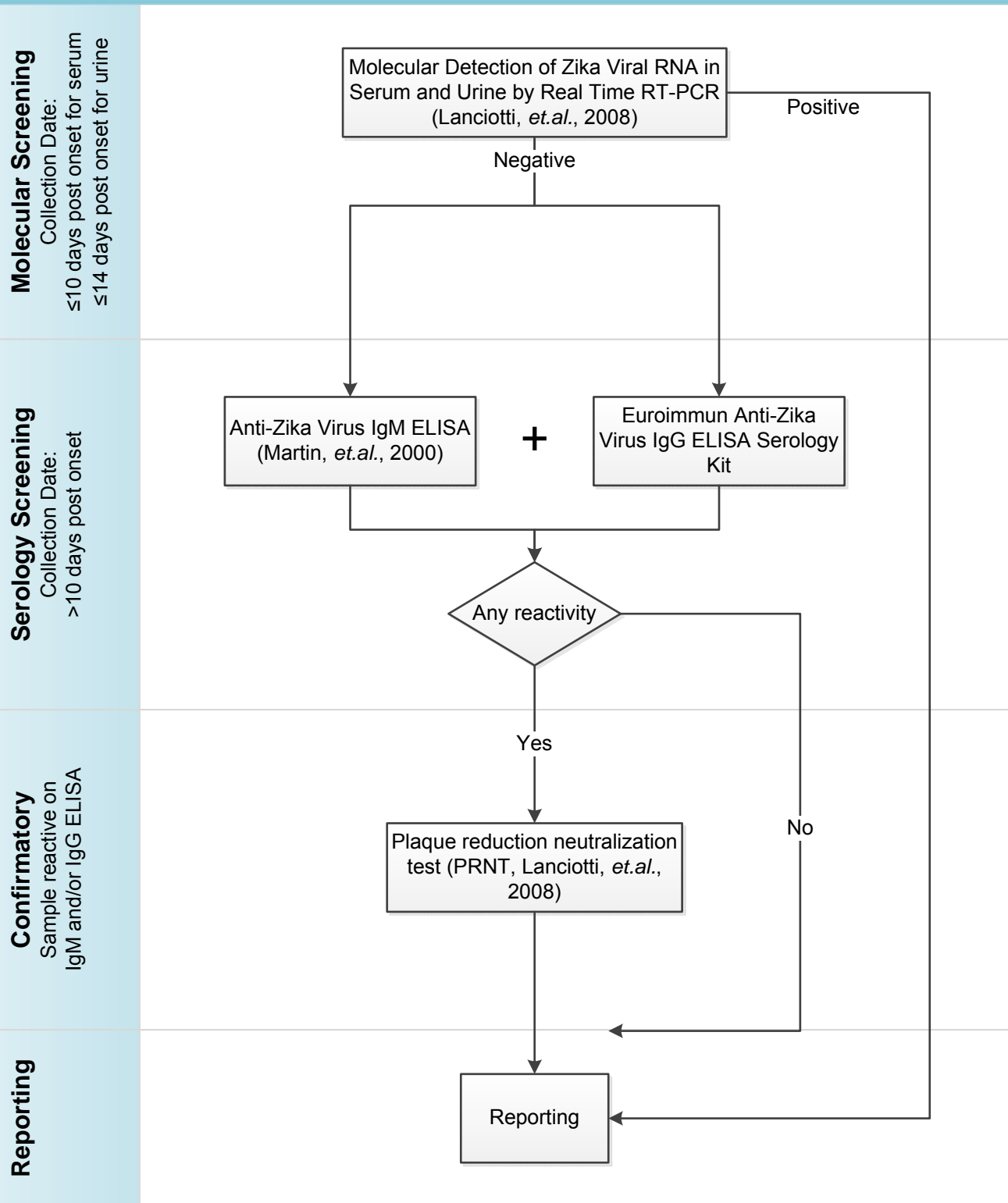


The Zika Virus Diagnostic Algorithm Used at the NML



A.Triage

Reviewing the requisitions

1. Information captured in LIMS:
 - a. Specimen type if not serum, i.e. plasma, urine, bone marrow, CSF, semen, placental tissue, amniotic fluid, umbilical cord.
 - i. NOTE: Serum **OR** EDTA Plasma should be sent. Both sample types are not required.
 - ii. Paired samples will be tested if provided; note that the samples are paired and ensure a minimum of 14 days between collection dates.
 - iii. If matched acute serum and urine samples are provided, both will be tested.
 - b. Pregnancy status.
 - c. Dates to log: collection, onset and travel. Be sure unambiguous dates are used. E.g. either YYYY-MM-DD or with the month spelled out or abbreviated, provided it is done so in such a way that there is no confusion as to what digits represent the year and/or date (E.g. Nov. 9/10 or 2010-Nov-9 are suitable. 10-Nov-09 is NOT as one does not know for certain which number is the year vs. the date).
 - d. Interesting notes to be included in comments: previous results, abnormal ultrasound, miscarriage, sexual transmission, etc.

***If a specimen is thought to be high priority based on the notes, the requisition should be flagged with a sticky note to tell the logger to forward the AR16-number to OCNML Planning as soon as it is received**

Process Improvement: Where communications have occurred between the Provincial Lab and the NML regarding the testing of a specimen, the Provincial Lab will include a copy of the email discussion with the requisition, or otherwise clearly note. This will be flagged by Triage to ensure it is addressed as a priority sample/sample of interest.

2. Note the test(s) to be performed somewhere visible on the bottom half of the requisition.
 - a. Test to be done is determined using the acceptance criteria (below).

- b. The Zika virus test abbreviations are Zika PCR, Zika M, **Zika G**, Zika PRNT.
- c. If tests for other viruses are requested they should also be noted (Dengue, Yellow Fever, etc.).
 - i. Note that some provinces do their own testing for some viruses other than Zika. For these provinces only the Zika virus tests need to be done/noted and the other tests can be ignored. Check with Viral Zoonoses Lab for each province.

Process Improvement: NML requisition forms will have the “Pregnancy” field more prominently displayed.

Criteria for acceptance or rejection of the specimens

1. Specimens are ACCEPTED for testing if all criteria are met:
 - Travel to an endemic area/area of concern AND symptoms;
 - AND/OR Pregnant;
 - OR Symptomatic patients without travel history, who have had sexual contact with a confirmed Zika positive case.
 - a. Endemic areas/areas of concern include all South American countries, all Caribbean Islands, Mexico, SE Asia, Africa, Micronesia, and Polynesia.
 - b. Accept specimens from asymptomatic pregnant women **if travel is within 3 months of conception.**
 - c. Conceiving is not equivalent to pregnant UNLESS it is by IVF.
 - d. Pregnant woman who have had unprotected sexual contact with a Zika infected male, or a male who has travelled to a Zika affected area in the last **3** months.
 - e. **Requisition must include travel dates AND/OR symptom onset date.**
 - f. If no symptoms onset date is listed, use the travel date in lieu to determine specimen acceptability.
 - g. **Reactive Zika IgM AND/OR Zika IgG samples can be submitted to NML for Zika PRNT, requisition must include reactive results and meet testing criteria.**
2. The collection dates must fall within the required timelines for the possible tests:
 - a. Urine samples that must have been collected within 14 days from travel/symptom onset are destined for Zika PCR.

- b. Tissue samples will be tested by Zika PCR only.
- c. Serum samples that have been collected within 10 days of travel/symptom onset are destined for both Zika PCR and Zika IgM.
- d. Serum samples that have been collected from 11 days to within 3 months of travel/symptom onset are tested for Zika IgM and Zika IgG.
- e. Serum samples that have been collected after 3 months from travel/symptom onset are destined for Zika PRNT.
- f. Serum samples that are reactive by Zika IgM AND/OR Zika IgG ELISAs will be sent for Zika PRNT.
- g. For all other specimen types consult Viral Zoonoses Lab for timeline and tests.

Processes Improved: The NML now contacts all Provincial Laboratories only via email to notify of REJECTED samples. Emails are kept for quality assurance purposes.

3. Specimens are REJECTED for testing if criteria are not met. The following scenarios would be REJECTED:
 - NO Travel to endemic area/area of concern, UNLESS the request is for a symptomatic patient who has had sexual contact with a Zika confirmed positive case, or is pregnant.
 - Travel to an endemic area/area of concern and asymptomatic, UNLESS the request is for a patient is pregnant.
 - Otherwise not meeting the criteria listed in *Criteria for acceptance* (1.).
- a. Requisition does not list travel dates OR symptom onset date (no onset date required for asymptomatic pregnant females).
- b. Specimens are collected outside the date ranges listed above.

Process Improvement: NML requisition forms include “*Travel Date*” (YYYY-MM-DD) beside “*Travel Location*” field. To assist provincial laboratory transcribers, modifications will be made to clearly indicate “*Travel Return Date*”.

Rejected Specimen Procedure:

1. Where a sample or requisition fails to meet the ACCEPTANCE criteria, it is placed into the REJECTED requisition folder.

- a. The Provincial Laboratory will receive an email from the Viral Zoonoses Laboratory notifying them of rejected sample numbers, within 48 business hours of sample receipt at the NML. Supplemental information required for ACCEPTANCE will be requested from the Provincial Laboratory.
- b. The submitting laboratory is given 30 calendar days to provide the missing information.
- c. Once missing information is provided, the technician will add the information to the requisitions and forward the requisition to be logged.
- d. Where the submitting laboratory fails to provide the missing information within 30 calendar days, the NML will generate a REJECTED sample report, and forward via fax to the provincial laboratory.
- e. If no corrections are received from the Provincial Laboratory, the requisition is filed and the sample discarded at a later date.

Process Improvement: The NML will forward the REJECTED sample report via fax to the Provincial Laboratory after 30 calendar days. Sample discard will be postponed an additional 30 calendar days to allow the Provincial Laboratory to review the REJECTED sample reports and submit any changes.