JANUARY 28, 2020


# Montana Laboratory Sentinel

Updates from the MT Laboratory Services Bureau, 800-821-7284, www.lab.hhs.mt.gov

## NEW!!!

### HIV-1 RNA Quantitation nucleic amplification test (NAT) (*Requires PLASMA)*

The Montana Public Health Laboratory recently implemented HIV RNA NAT testing for the confirmation of current HIV infection, as well as for monitoring treatment status. Following the CDC recommended algorithm, laboratories should conduct initial testing for HIV with an FDA-approved antigen/antibody immunoassay that detects HIV-1 and HIV-2 antibodies and HIV-1 p24 antigen. No further testing is required for specimens that are non-reactive on the initial immunoassay. However, if there is a possibility of a very early infection leading to a non-reactive initial antigen/antibody immunoassay, such as when a recent HIV exposure is expected or reported, then the HIV RNA NAT test should be conducted, or a new specimen should be requested for repeat testing following the algorithm.

Any specimens that are reactive on the initial antigen/antibody immunoassay and non-reactive or indeterminant on the HIV-1/HIV-2 antibody differentiation assay, will be automatically reflexed to the HIV RNA NAT test to confirm HIV status.

In addition to diagnosis, the HIV RNA NAT test can be used to monitor the clinical response to antiretroviral therapy (ART) for patients with known HIV infection. Viral load monitoring of patients on ART helps ensure early diagnosis and confirmation of ART failure and enables clinicians to take an appropriate course of action for patient management. Specimens from newly identified cases of HIV will be automatically reflexed to the HIV RNA NAT test to determine viral load.

**This new assay requires PLASMA for testing.** If you have a highly suspect patient or a positive rapid screen, it is best to submit plasma for all HIV testing. This way the patient will not need to be recollected if an HIV RNA NAT test is needed

**Specimen Collection for HIV RNA NAT:**

EDTA or Acid Citrate Dextrose (ACD) anticoagulants or
Plasma Preparation Tubes (PPTs)

Whole blood can be stored at 2° C to 30° C and must be centrifuged within 24 hours of collection. Separate the plasma from the pelleted red blood cells following the manufacturer's instructions for the tube being used. Ship the separated plasma at 2° C to 8° C within 3 days of collection.

## NEW!!!

### Updated Form for Adding on Tests for Mycobacteriology

We recently updated the "Add-on Test" request form for use when requesting additional testing on *Mycobacteria* spp. isolates. This updated version provides a little more clarity on the testing choices, including susceptibility testing for *Mycobacterium avium complex* (MAC) isolates. Please click here to see and/or print the updated form and let us know if you have any questions.

### COMING SOON!!

Updates to the on-line Laboratory Services Manual (now available on our website:
https://dphhs.mt.gov/publichealth/LaboratoryServices/PublicHealthLabTesting
Updates to the Public Health Laboratory Request Form
Updates to the Supply Order Form

The updated material will be available on our website by the end of January.

https://dphhs.mt.gov/publichealth/LaboratoryServices/PublicHealthLabTesting

**For any questions or concerns, please contact us at 800-821-7284 or 406-444-3444**

## Reminders!!

### Patient Manifest

Remember to include a patient manifest with all specimens submitted to the Montana Public Health Laboratory. Although we are receiving manifests from the majority of you, there are still a few who are not submitting manifests as requested. We are asking you to please take a moment to print a manifest from your patient information system or use the generic manifest we provided. If you need another copy of the generic patient manifest form, just give us a call. This requirement was implemented to help us ensure that we have received all specimens sent on given day. Thank you again to those who have been submitting manifests on a regular basis. This process has already proven to be beneficial on several occasions.

### LARGE Specimen transport Bags

For those facilities serviced by the State courier, we are still requesting that you try using the LARGE green customized specimen transport bags when you are sending multiple specimens. The bags turned out quite a bit bigger than we anticipated, and we realize the size is not ideal, but we are still hoping to use this process to increase efficiency of transit, security and reconciliation of specimens. Placing all smaller specimen transport bags into one larger transport bag from each facility has really helped with the tracking of specimens. Please let us know if you have any questions or are in need of more bags.

## Hepatitis C RNA Quantitation

Just a reminder that the Montana Public Health Laboratory has implemented Hepatitis C RNA testing for confirmation of current Hepatitis C Virus (HCV), as well as for monitoring treatment status. Following CDC's recommended algorithm, all positive HCV antibody screens will now be reflexed to the HCV RNA assay to determine patient status. If you have any questions about this testing, please give us a call.

## Reverse Syphilis Testing Algorithm

In September 2019, the Montana Public Health Laboratory implemented the "reverse syphilis testing algorithm" for the screening and serodiagnosis of syphilis. Adhering to this protocol requires that patient specimens are first screened with a treponemal antibody assay (IgG), where non-reactive specimens do not require further testing. If the initial IgG is reactive, only then are specimens tested by a quantitative VDRL which is used to assess disease activity. Discrepant IgG and VDRL results are resolved by a second treponemal test (TP-PA) as recommended by the Centers for Disease Control.

We have had a few instances where a facility that is performing a **total antibody** (IgG & IgM) assay submits a positive specimen for confirmatory testing and the specimen is non-reactive with our treponemal antibody assay (IgG). In this scenario, it is possible that the total antibody test is only detecting IgM but was performed in the window period before IgG antibody production. Standalone IgM testing for syphilis is not recommended due to higher potential of non-specific cross-reactivity to other conditions such as pregnancy, HIV, and other autoimmune disorders.

Another concern is that the overall sensitivity for both treponemal immunoassays *and* non-treponemal tests (VDRL and RPR) can be decreased during primary syphilis. An initial negative IgG antibody result cannot exclude incubating or early syphilis due to a sero-negativity window of up to 4 weeks during primary syphilis. In the absence of detectable IgG, VDRL titers may also be inaccurate which is why MTPHL **will not** be performing VDRL titer testing when a negative IgG immunoassay is resulted. The CDC recommends that at-risk or suspect patients with an initial negative syphilis immunoassay be **recollected and tested 2-4 weeks later to confirm disease status** and ensure that adequate antibody titer formation has occurred. As with any assay, diagnosis should not be based solely on the assay results and should be used in conjunction with a patient's clinical signs, symptoms and risk factors.

For further information on testing and diagnosis recommendations please visit these sites:

https://www.cdc.gov/std/tg2015/syphilis.htm

https://www.aphl.org/aboutAPHL/publications/Documents/ID_Suggested_Syphilis_Reporting_Lang_122015.pdf