

# VARHS Project Summary

## *What is VARHS?*

VARHS (Variant, Atypical and Resistant HIV Surveillance) is a CDC-funded surveillance initiative aiming to incorporate HIV drug-resistant genotype testing (specifically sequencing the reverse transcriptase (RT) and protease regions of the *pol* gene of HIV) into routine diagnostic HIV testing protocol statewide.

## *Who participates?*

The VARHS study population encompass ALL Michigan residents over 12 years of age who have their first confidential HIV diagnosis identified through the Michigan Department of Community Health's (MDCH) two HIV Regional laboratories (Detroit and Grand Rapids) or major clinical sites statewide, and who are not known to have been exposed to antiretroviral therapy. Sites are being added until HIV drug-resistant genotype testing is part of routine HIV testing protocols throughout Michigan.

## *Why is VARHS important?*

The public health implications of baseline (at diagnosis) resistance testing are great as previous studies indicate a rise of resistant strains among infected persons and that perhaps as many as 15% of newly infected individuals become infected with a resistant strain of HIV. Baseline testing is important from a clinical perspective because as infection progresses in the individual the ability to detect mutant strains becomes increasingly difficult (wild-type virus takes over obscuring less-fit mutant strains from detection). However, when the individual enters into an initial treatment regimen these drug-resistant mutants will surface and can cause treatment failure (providing an opportunity for new drug-resistant mutations to surface). Baseline resistance testing is routine in many Canadian provinces and European nations where the prevalence of HIV drug-resistant strains exceeds 10%. Further, both the US Department of Health and Human Services and the US panel of the International AIDS Society recommend resistance testing for newly infected and chronically infected drug naïve individuals.

## *How will it affect the services offered to individuals seeking HIV testing in Michigan?*

The MDCH human subjects committee has ruled that there is no reason for consent to be obtained for VARHS testing as it presents very minimal risk to participants and is a part of routine surveillance in Michigan. No additional blood draw is required and no additional patient information outside of routine surveillance is collected. Thus, ALL positive specimens from individuals not previously reported as HIV positive in the last 3 months, (regardless of stage of disease), will be genotyped. A benefit to patients is that genotype test results with interpretations (usually costing \$300) are returned free to a health care provider designated by the participant at post-test counseling within 1 month (and can be designated up to 5 years after the test is conducted).

## *What is required of HIV specimen collection staff?*

VARHS relies on genotyping technology that necessitates specific specimen collection and handling procedures. The following summarizes what will be the new HIV testing protocol in order to accomplish VARHS testing:

- Blood should be drawn in tubes large enough to capture **4mL of SERUM** designated for HIV testing (8.5-10mL tubes)
- Whole blood specimens should be **centrifuged and serum removed from the clot (using serum separator tubes or by pouring over) within 24 hours**
- Serum specimens in new **5mL polystyrene snap-top tubes** should ideally be delivered to the HIV diagnostic testing laboratory within **48 hours from blood draw**
- Information relating to specimen handling must be recorded, by specimen collection staff, on the **backside of new yellow laboratory test request forms** that accompany specimens to the HIV diagnostic testing laboratory
- At post-test counseling patients can either complete the **VARHS authorization sheet** that allows them to designate a clinician that will receive their VARHS test results or they can take the sheet with them and can contact MDCH up to 5 years after the test was conducted to designate a clinician that will receive their VARHS test results
- The **MDCH Regional lab ID number MUST be written on the lower right side of the post-test info sheet** (where designated) by counselor during post-test counseling or VARHS test results will not be released by MDCH

### **For more information contact:**

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