NAHLN Sustained Laboratory Capacity October 2024

Please note: This procedure may be revised as needed.

The National Animal Health Laboratory Network (NAHLN) is a partnership of state and federal diagnostic laboratories that provides investigational and surveillance testing for high consequence agricultural pathogens. In the event of an animal disease outbreak, early detection is critical to contain the disease as quickly as possible. Additionally, testing the surge of samples collected following a confirmed detection is essential to identify the extent of the outbreak and to provide guidance to those tasked with making decisions regarding mitigation steps. NAHLN laboratories are asked to maintain preparedness which includes a rapid and sometimes prolonged response. The ideal capacity of a laboratory is the maximum results output the lab can sustain, based on the approved equipment, personnel, and materials available, if sample collection, submission, accessioning, testing, and resulting/messaging happen such that samples arrive batched early in the day with all needed information. Determining the true capacity of a laboratory requires an understanding how the ideal capacity may be affected by circumstance.

A. Ideal Maximum Capacity for a NAHLN Laboratory

- Capacity = equipment + personnel + materials + number of shifts
- 3 Personnel (24 personnel hours), 1 approved extraction machine (may be approved through a deviation), 2 thermocyclers, 1 8-hour shift = 1 unit // 1 unit can provide 3-4 plates/ shift = approx. 300-400 tests / shift
 - Included instrumentation must be approved for specific assay.
 - Minimum of 1 Proficiency Tested analyst included
 - 24 personnel hours during each 8h shift, must be available not dedicated to outbreak testing
 - Non-PT'ed personnel can do the following tasks:
 - Laboratory tasking: prepare plates, add washes, elution, make lysis buffer, beads, make master mix, aliquot into tube/plate, any steps prior to sample handling
 - Support tasking: accessioning, IT/LIMS, billing, procurement, section head, results reporting, etc.
- Independently determined by each laboratory for each disease and used to calculate regional capacity for the NAHLN

B. Circumstances that Reduce Laboratory Capacity

- Sample Delivery- inconsistent and multiple times per day
- Issues with sample shipments (missing, incorrectly identified, or leaking samples)
- Submission Form missing or incomplete information
- Need to perform significant data entry to message results (need for data entry personnel)
- Loss of ability for high throughput testing- multiple sample types or multiple tests per disease
- Retests, positive samples requiring up to 3 additional tests (H5, H7, H5 2.3.4.4b)
- Work completed in BSL3 may slow through-put

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C. Circumstances that Affect Laboratory Capacity

- Stockpiling of needed materials to maintain testing at capacity for 15-30 days
 - Actual needs, based on items listed in Section B., not close to nearing lab calculated capacity
- Rolling inventory for items that expire large potential for waste and reagents are very costly
 - Items could be shuttled to other labs that would/could use the reagents prior to expiration with intensive management
- Management or maintenance of stockpile
- Potential for sharing (reagents, equipment, personnel) within network based on outbreak location
- Electronic submission process including required messaging data points
- Consistent delivery schedule of samples to the laboratory, ideally early in the shift
 - Allowing for runs of full plates and reduction in reagent waste
- Consistent and clear communication on reason for testing
- Equipment changes breakdowns or additions
- Personnel availability annual leave, sick leave, new hires, etc.

D. Maintaining a Stockpile to meet expected Capacity

- Location:
 - Local at each laboratory to maintain testing for 2 weeks
 - o Regionally maintained at one NAHLN laboratory for transport to NAHLN labs as needed
 - National:
 - National Veterinary Stockpile
 - National Veterinary Services Laboratories
 - National Animal Vaccine and Veterinary Countermeasures Bank
 - Vendors
- Maintenance of rolling inventory
 - o Additional personnel needed
 - Space availability- Contents of stockpile determined locally, regionally, Nationally
 - Standardized tracking- software, barcodes, QR codes, managed in the APHIS Laboratory Portal, etc.