

REQUEST TO DEVIATE FROM A NAHLN DOCUMENT

NAHLN Laboratories must submit a completed “Request to Deviate From a NAHLN Document” form prior to off-protocol use of NAHLN assays, work instructions or other NAHLN document. To submit a form, the NAHLN Laboratory must complete blocks A through E. This instruction guide will provide information on how to complete the form, how to submit the form, and how the decision on the request will be reported back to the submitting NAHLN Laboratory.

Completing the form:

Block A:

- Laboratory name:
- Laboratory Director:
- Laboratory Director’s Telephone number:
- Laboratory Director’s e-mail address:

Block B:

- Enter date range or period of time for when deviation is requested. It is acceptable to list “until next SOP version released”.
- Enter the associated NAHLN SOP number and version number. Only include one SOP number per deviation request.
- Enter the associated NAHLN SOP name.

Block C:

- Enter description of the proposed planned deviation including specific information.

Block D:

- Enter a technical justification for the proposed planned deviation. Provide an explanation of the verification process used to determine that the deviation will not affect test results.

Block E:

- Mark the appropriate box (Yes / No) to denote if your deviation, if approved, can be publicly posted on the APHIS Portal in the General Library.
- Laboratory Director’s Review requires both signature and date.

Submitting the form to the NAHLN Program Office

- Scan completed form and e-mail to: nahln@usda.gov.
- Use the following for the subject line of the e-mail submission:

Request immediate review: Submitting a “Request to Deviate from a NAHLN Document”

Reporting of approval or denial to the submitting NAHLN Laboratory (Block F)

- The submitted request will be reviewed and signed by the NVSL Reference Laboratory and the NAHLN Coordinator/designee.
- The submitted request will either be checked as “deviation approved” or “deviation denied”. NVSL Officials must concur in order for deviation to be accepted.
- If the deviation is approved, the NVSL Reference Laboratory will mark the appropriate box (Yes / No) to denote if the deviation can be publicly posted to the APHIS Portal.
 - The NAHLN Laboratory and NVSL Reference laboratory must concur for the deviation to be publicly posted.
- If the deviation is denied, the reason for the denial will be included in the Justification box.
- The reviewed form will be signed and returned to the submitting laboratory by e-mail.

REQUEST TO DEVIATE FROM A NAHLN DOCUMENT

USDA, APHIS, VS recognizes that NAHLN laboratories may be requested to deviate from a NAHLN testing standard operating procedure or other NAHLN document. NAHLN Laboratories must submit this completed form to the NAHLN Program Office for approval prior to deviating from the approved use of NAHLN assays.

The completed form must be scanned and e-mailed to: nahln@aphis.usda.gov.

Submitted forms will be reviewed, and the submitting NAHLN Laboratory will receive the signed document (approved or denied) by e-mail.

A.	Laboratory Name:	
	Laboratory Director:	
	Laboratory Director's Telephone number:	
	Laboratory Director's e-mail Address	

B.	Date range of planned event (or period of time deviation will be performed):	
	NAHLN SOP & Version Number (one per form):	
	NAHLN SOP Name:	

C.	Description of the proposed planned deviation:
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D.	Technical justification for the proposed planned deviation:
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By signing this form, the Laboratory Director is:

- ✓ Requesting a planned deviation from the listed NAHLN Document.
- ✓ Understands the reporting requirements associated with conducting tests off-protocol and will report to the client that the test used was not validated for the specific deviation.
- ✓ Understands that no deviations are allowed without approval from NVSL. **Failure to comply with all regulations and policies by any party may result in immediate loss of the laboratory's approval to conduct NAHLN testing.**
- ✓ Understands that this deviation, if agreed to by both the NAHLN laboratory and the NVSL Reference Laboratory, will be posted to the APHIS Portal in the General Library for public access and review.
- ✓ Understands that this deviation, if approved, will expire upon the release date of a new NAHLN SOP version. It is the requesting laboratory's responsibility to renew the request to deviate if still needed.

E.	Laboratory Director's Review	Agree to publicly post deviation request to APHIS Portal General Library?	<input type="checkbox"/> YES	<input type="checkbox"/> NO	
		Signature and date			

F.	NVSL & NAHLN Review			
	NVSL Reference Laboratory:	Agree to publicly post deviation request to APHIS Portal General Library?	<input type="checkbox"/> YES	<input type="checkbox"/> NO
		<input type="checkbox"/> Deviation Approved	<input type="checkbox"/> Deviation Denied	
		Justification:		
	Signature and Date			
	NAHLN Coordinator/designee:	<input type="checkbox"/> Deviation Approved	<input type="checkbox"/> Deviation Denied	
		Justification:		
		Signature and Date		