SOP Number **1**

SOP Title **Sample Receiving and Handling**

	NAME	TITLE	SIGNATURE	DATE
Author	**Chang-Hyun Kim**	**Lab specialist**		**8/15/2014**
Reviewer	**Ephantus J. Muturi**	**Director**		**8/15/2014**
Authoriser	**Ephantus J. Muturi**	**Director**		**8/15/2014**

Effective Date:	**8/15/2014**
Review Date:	**2/2/2015**

READ BY			
NAME	**TITLE**	**SIGNATURE**	**DATE**

1. PURPOSE

This procedure is to ensure both the safety of operator(s) and the integrity of samples shipped from NEON facilities.

2. INTRODUCTION

Mosquito samples collected by various NEON facilities are shipped to Medical Entomology Laboratory for taxonomic identification and/or pathogen testing. It is critical to maintain the integrity of mosquito samples for accurate testing results. In order to keep the integrity, samples are usually shipped in packages that contain material(s) to keep the samples cold or frozen. Prompt storage of the samples is necessary upon receiving. At the same time, a necessary precaution should be taken to protect operator(s) from getting injury(s) by the freezing or chilling material(s).

3. SCOPE

This procedure is for mosquito samples submitted by NEON facilities. The samples for archiving only are excluded from this procedure and a separate SOP for preserving and archiving must be followed.

4. DEFINITIONS

Not applicable.

5. RESPONSIBILITIES

Operator(s) of this procedure must ensure the availability of storage space, the timely storage of the samples and the documentation of receiving.

6. SPECIFIC PROCEDURE

(1) Operator(s) of this procedure must ensure that there is sufficient storage space in ultra-low temperature (-80°C) freezer(s) prior to receiving shipment from NEON facilities.

(2) Upon receiving the shipment, operator(s) must check the condition of shipment such as status of mosquito samples, presence of packaging materials and presence of temperature control materials.

(3) Depending on the temperature in which samples are, operator(s) must wear proper protection such as oven gloves, lab coat and examination gloves.

(4) While keeping the samples in the same temperature of shipment, operator(s) must check whether all mosquito samples match the information recorded on shipment datasheet, which is submitted by NEON facilities.

(5) Operator(s) must store the mosquito samples at ultra-low temperature (-80°C) freezer before the temperature control materials in shipping package run out of their capacity.

(6) Operator(s) must document the condition of shipment and the location of storage. The required information for documentation is number of vials, condition of samples and storage location.

7. FORMS/TEMPLATES TO BE USED

This procedure requires datasheet submitted by NEON facilities.

8. INTERNAL AND EXTERNAL REFERENCES

8.1 Internal References

Not applicable.

8.2 External References

Not applicable.

9. CHANGE HISTORY

SOP no.	Effective Date	Significant Changes	Previous SOP no.
1	**8/15/2014**	**Initial SOP**	**New**
1	**2/2/2015**	**Revised to meet requirements from NEON**	**1**

SOP Number **2**

SOP Title **Sample Preserving and Archiving**

	NAME	TITLE	SIGNATURE	DATE
Author	**Chang-Hyun Kim**	**Lab specialist**		**8/15/2014**
Reviewer	**Ephantus J. Muturi**	**Director**		**8/15/2014**
Authoriser	**Ephantus J. Muturi**	**Director**		**8/15/2014**

Effective Date:	**8/15/2014**
Review Date:	**2/2/2015**

READ BY			
NAME	**TITLE**	**SIGNATURE**	**DATE**

1. PURPOSE

This procedure is to ensure the integrity of mosquito samples from NEON after taxonomic identification. In addition, this procedure can be followed for the submission of archive samples.

2. INTRODUCTION

After taxonomic mosquito identification and pathogen testing, remaining mosquito samples are to be stored in an ultralow temperature (-80°C) freezer for archiving. In addition, following the shipment of mosquito samples for archiving, Medical Entomology Laboratory, INHS, UIUC will preserve the samples in an ultralow temperature (-80°C) freezer. For archiving, it is critical to maintain the integrity of mosquito samples and to keep track of locations where the samples are stored.

3. SCOPE

This procedure is for mosquito samples submitted by NEON facilities for archiving purpose only and for mosquito samples remaining after taxonomic identification and pathogen testing. The samples for taxonomic identification or pathogen testing are excluded from this procedure and a separate SOP for sample receiving and handling must be followed.

4. DEFINITIONS

Not applicable.

5. RESPONSIBILITIES

Operator(s) of this procedure must ensure the availability of storage space, the timely storage of the samples and the documentation of storage location.

6. SPECIFIC PROCEDURE

(1) Operator(s) of this procedure must ensure that there is sufficient storage space in ultra-low temperature (-80°C) freezer(s) prior to storing samples or receiving shipment from NEON facilities.

(2) Handling mosquito samples must be carried out on an operating chill table set at 0°C.

(3) Operator(s) must use cryo vials of appropriate size depending on the number of mosquitoes in the same year of collection, sex, taxonomic identification, bout and site. The guide line of proper vial size is as following:

Number of mosquitoes	Recommended size of cryo vial
1-50	2-ml
51-200	5-ml
201-500	15-ml*

* Multiple vials can be used for the mosquitoes exceeding 500. The number of mosquitoes in each vial cannot be exceeded more than 500.

(4) Operator(s) must label cryo vial based on the site, year of collection, taxonomic identification when it is filled with mosquito samples.

(5) Operator(s) must place the cryo vials filled with mosquito samples in a cryo storage box of which size can accommodate the size of cryo vial.

(6) Operator(s) must label the cryo storage box based on location of cryo box in an ultra-low temperature freezer. For example, if the cryo vial is put in 15th cryo storage box located in the second shelf of freezer A, the label should be “A2Box15”.

(7) Cryo storage boxes must be arranged in numerical order.

(8) Operator must record the location of the vial in datasheet submitted by NEON facilities by indicating the label on the cryo storage box.

7. FORMS/TEMPLATES TO BE USED

This procedure requires datasheet submitted by NEON facilities.

8. INTERNAL AND EXTERNAL REFERENCES

8.1 Internal References

Not applicable.

8.2 External References

Not applicable.

9. CHANGE HISTORY

SOP no.	Effective Date	Significant Changes	Previous SOP no.
2	**8/15/2014**	**Initial SOP**	**New**
2	**2/2/2015**	**Revised to meet requirements from NEON**	**2**

SOP Number **3**

SOP Title **Sample Counting and Sorting**

	NAME	TITLE	SIGNATURE	DATE
Author	**Chang-Hyun Kim**	**Lab specialist**		**8/15/2014**
Reviewer	**Ephantus J. Muturi**	**Director**		**8/15/2014**
Authoriser	**Ephantus J. Muturi**	**Director**		**8/15/2014**

Effective Date:	**8/15/2014**
Review Date:	**2/2/2015**

READ BY			
NAME	**TITLE**	**SIGNATURE**	**DATE**

1. PURPOSE

This procedure is to estimate the number of mosquitoes that have been excluded from taxonomic identification or pathogen testing when/if the number of mosquitoes is greater than 500.

2. INTRODUCTION

After taxonomic mosquito identification and pathogen testing, the number of remaining mosquito samples is to be estimated before archiving in an ultralow temperature (-80°C) freezer. At the medical Entomology Laboratory, INHS, UIUC, an average weight of a mosquito is utilized to calculate the estimated number of mosquitoes from the total weight of mosquitoes exceeding 500.

3. SCOPE

This procedure is for estimating the number of mosquito samples that are remaining from taxonomic identification or pathogen testing. Samples with less than 500 mosquitoes must be counted individually.

4. DEFINITIONS

Not applicable.

5. RESPONSIBILITIES

Operator(s) of this procedure must understand the mathematical calculation, and must ensure the integrity of mosquito samples, the timely storage of the samples and the documentation of the results.

6. SPECIFIC PROCEDURE

(1) Operator(s) visually estimate the number of mosquitoes in a container. Samples in excess of 500 mosquitoes will be weighed for mathematical estimation of sample size. Samples with less than 500 mosquitoes must be counted individually.

(2) Handling mosquito samples must be carried out on an operating chill table set at 0°C. Mosquito samples can only be taken off of the chill table when they are to be weighed and the duration cannot exceed 5 minutes.

(3) Multiple containers from same site, bout and trap can be weighed at the same time.

(4) Operator(s) must transfer the mosquito samples to cryo vial with an appropriate size. The guide line of proper vial size is as following:

Number of mosquitoes	Recommended size of cryo vial
1-50	2-ml
51-200	5-ml
201-500	15-ml*

* Multiple vials can be used for the mosquitoes exceeding 500. The number of mosquitoes in each vial cannot be exceeded more than 500.

(5) Operator(s) must label cryo vial based on the site, year of collection, taxonomic identification (usually “unknown”) when it is filled with mosquito samples.

(6) Operator(s) must place the cryo vials filled with mosquito samples in a cryo storage box of which size can accommodate the size of cryo vial.

(7) Operator(s) must label the cryo storage box based on location of cryo box in a ultra-low temperature freezer. For example, if the cryo vial is put in 15th cryo storage box located in the second shelf of freezer A, the label should be “A2Box15”.

(8) Cryo storage boxes must be arranged in numerical order on a shelf of an ultra-low temperature (-80°C) freezer.

(9) Operator must record the location of the vial in datasheet submitted by NEON facilities by indicating the label on the cryo storage box.

7. FORMS/TEMPLATES TO BE USED

This procedure requires datasheet submitted by NEON facilities.

8. INTERNAL AND EXTERNAL REFERENCES

8.1 Internal References

Not applicable.

8.2 External References

Not applicable.

9. CHANGE HISTORY

SOP no.	Effective Date	Significant Changes	Previous SOP no.
3	**8/15/2014**	**Initial SOP**	**New**
3	**2/2/2015**	**Revised to meet requirements from NEON**	**3**

SOP Number **5**

SOP Title **Reagents**

	NAME	TITLE	SIGNATURE	DATE
Author	**Chang-Hyun Kim**	**Lab specialist**		**8/15/2014**
Reviewer	**Ephantus J. Muturi**	**Director**		**8/15/2014**
Authoriser	**Ephantus J. Muturi**	**Director**		**8/15/2014**

Effective Date:	**8/15/2014**
Review Date:	**2/2/2015**

READ BY			
NAME	**TITLE**	**SIGNATURE**	**DATE**

1. PURPOSE

This procedure is to ensure the quality of reagents that are used for pathogen testing.

2. INTRODUCTION

For mosquito taxonomic identification, mosquito samples that are preserved at -80°C essentially will be taken out of the freezer and identified to species using a light microscope. It is critical to keep the integrity of mosquito samples during the process in order to maintain integrity of downstream procedures.

3. SCOPE

This procedure should be followed for all chemical reagent preparation by Medical Entomology Laboratory, INHS, UIUC.

4. DEFINITIONS

Not applicable.

5. RESPONSIBILITIES

Operator(s) must comply with the requirements of Division of Research Safety, UIUC.

6. SPECIFIC PROCEDURE

(1) Place mosquito samples on an operating chill table set at 0°C.

(2) An enamel pan lined with paper towel must be placed on operating chill table set at 0°C for at least 15 minutes prior to microscopic examination. Operator(s) place 10 2-ml snap-cap tubes on the chill table in order to pre-chill the tubes before collecting mosquitoes after taxonomic identification.

(3) Operator(s) must place mosquito samples from a vial on the enamel pan lined with paper towel and randomly select mosquitoes for identification. Total number of mosquitoes for identification is depending on the site and the number of containers. The guide line determining the number of mosquitoes is as following:

Situation	Number of mosquitoes for identification
Single vial from a SC site	500
If visual estimation is over 500 in a vial	300
Multiple vials from a SC site	300/vial

(4) Mosquito samples should only be taken off of the chill table to be examined under a microscope. Examination under the microscope is not to exceed 5 minutes in duration.

(5) Operator(s) must label a pre-chilled 2-ml snap-cap tube based on the site, year of collection, trap number and taxonomic identification. Each tube may contain up to 50 mosquitoes for each sex and identification. If there are more than 50 mosquitoes, multiple tubes can be created for the mosquito species and sex. Mosquitoes with different identification must be separated by an individual tube and be labelled accordingly.

(6) Operator(s) must keep the snap-cap tubes in a 2-inch cardboard storage box labelled with site, bout, mosquito species and sex. The storage box must be kept in a -80°C freezer.

(7) Prior to storing the box in a freezer, multiple voucher specimen can be selected and be stored in a separate 2-ml snap-cap tube. The tube must be labelled with site, collection year, mosquito identification and sex. The total number of voucher specimen for each sex and species cannot exceed 10 per site in a given collection year. The snap-cap tubes with voucher specimen must be stored in a 2-inch paperboard storage box labelled with site and collection year. The storage box must be kept in a -80°C freezer.

(8) When mosquito taxonomic identification of a bout from a site is complete, operator(s) must pool the mosquitoes if they have same site, bout, sex and identification. For pooling, a single pre-chilled 15- or 50-ml tube labelled with site, year, bout, identification and sex must be used to collect the mosquitoes. The tubes must be put in a ziplock bag labelled with site, year and bout and be kept in a -80°C freezer.

(9) Operator(s) must record the location of the ziplock bag in datasheet submitted by NEON facilities. Also, operator(s) must enter the results from taxonomic identification and sample pooling into the datasheet submitted by NEON facilities.

7. FORMS/TEMPLATES TO BE USED

This procedure requires datasheet submitted by NEON facilities.

8. INTERNAL AND EXTERNAL REFERENCES

8.1 Internal References

Not applicable.

8.2 External References

Not applicable.

9. CHANGE HISTORY

SOP no.	Effective Date	Significant Changes	Previous SOP no.
4	**8/15/2014**	**Initial SOP**	**New**
4	**2/2/2015**	**Revised to meet requirements from NEON**	**4**

SOP Number **5**

SOP Title **Reagents**

	NAME	TITLE	SIGNATURE	DATE
Author	**Chang-Hyun Kim**	**Lab specialist**		**8/15/2014**
Reviewer	**Ephantus J. Muturi**	**Director**		**8/15/2014**
Authoriser	**Ephantus J. Muturi**	**Director**		**8/15/2014**

Effective Date:	**8/15/2014**
Review Date:	**2/2/2015**

READ BY			
NAME	**TITLE**	**SIGNATURE**	**DATE**

1. PURPOSE

This procedure is to ensure the quality of reagents that are used for pathogen testing.

2. INTRODUCTION

Pathogen testing involves multiple lab techniques utilizing chemical reagents for their optimal capacity. It is critical to keep the integrity of reagents in order to maintain the optimum performance of each lab techniques.

3. SCOPE

This procedure should be followed for all chemical reagent preparation by Medical Entomology Laboratory, INHS, UIUC.

4. DEFINITIONS

TE buffer: Tris EDTA buffer

TAE buffer: Tris Acetate EDTA buffer

5. RESPONSIBILITIES

Operator(s) must comply with the requirements of Division of Research Safety, UIUC.

6. SPECIFIC PROCEDURE

(1) Whenever possible, solvent used for preparing reagents used in pathogen testing must be nuclease-free molecular grade.

(2) Preparing PCR primers:

a) If the primers are in lyophilized form, centrifuge the tubes containing PCR primers for at least 1 minute at 10,000 × g.

b) Add TE buffer to have primer concentration at 100 µM (stock primer solution).

c) Take small aliquot of stock primer solution and dilute it to 10 µM by adding nuclease-free water (working primer solution).

d) Both stock and working primer solution must be kept in -20°C freezer.

(3) Preparing TAE buffer: Take an aliquot of stock TAE buffer (×50) and dilute it to ×1.

(4) Preparing 2% agarose in TAE buffer:

a) Weigh molecular grade agarose to predetermined mass.

b) Add ×1 TAE buffer and make even suspension of agarose.

c) Mark the container with level of agarose suspension.

d) Heat the agarose suspension until agarose completely melts.

e) Add deionized water to compensate any loss of water during heating process and mix well.

f) Pour 2% agarose to gel casting apparatus.

(5) Preparing Ethidium bromide staining solution:

a) Put 1000 ml deionized water in staining container

b) Add 50 µl 10 mg/ml Ethidium bromide solution (final concentration is 0.5 µg/ml).

c) Keep the container with staining solution at room temperature in a lightproof place.

d) When it becomes a month old, the staining solution must be discarded following the requirements of Division of Research Safety, UIUC.

7. FORMS/TEMPLATES TO BE USED

Material Safety Data Sheets (MSDS): MSDS provides both workers and emergency personnel with the proper procedures for handling or working with a particular substance. MSDS's include information such as physical data (melting point, boiling point, flash point, etc.), toxicity, health effects, first aid, reactivity, storage, disposal, protective equipment and spill/leak procedures.

8. INTERNAL AND EXTERNAL REFERENCES

8.1 Internal References

Not applicable.

8.2 External References

Not applicable.

9. CHANGE HISTORY

SOP no.	Effective Date	Significant Changes	Previous SOP no.
5	**8/15/2014**	**Initial SOP**	**New**
5	**2/2/2015**	**Revised to meet requirements from NEON**	**5**

SOP Number **6**

SOP Title **Primary Analytical Methods**

	NAME	TITLE	SIGNATURE	DATE
Author	**Chang-Hyun Kim**	**Lab specialist**		**8/15/2014**
Reviewer	**Ephantus J. Muturi**	**Director**		**8/15/2014**
Authoriser	**Ephantus J. Muturi**	**Director**		**8/15/2014**

Effective Date:	**8/15/2014**
Review Date:	**2/2/2015**

READ BY			
NAME	**TITLE**	**SIGNATURE**	**DATE**

1. PURPOSE

This procedure is to ensure the quality of primary analytical methods used for pathogen testing.

2. INTRODUCTION

When mosquito pools are submitted to Medical Entomology Laboratory, INHS, UIUC for arbovirus testing, they are assayed in two steps: First, RT-PCR is used to identify the arbovirus down to the family level. Second, Sanger DNA sequencing is used to identify the virus species/ or strain.

3. SCOPE

This procedure should be followed for all mosquito pools submitted to Medical Entomology Laboratory, INHS, UIUC for pathogen testing purposes.

4. DEFINITIONS

RT-PCR: Reverse transcriptase polymerase chain reaction
PCR master mix: Pre-made reagent solution for PCR which lacks reverse transcriptase, RNAse inhibitor, PCR primers and target nucleic acids.
PCR mix: Reagent solution containing all necessary ingredients for PCR except target nucleic acids.

5. RESPONSIBILITIES

Operator(s) must comply with the requirements of Division of Research Safety, UIUC.
Operator(s) must use aseptic technique to avoid contamination.

6. SPECIFIC PROCEDURE

(1) Operator(s) must create a layout that indicates the location of mosquito samples on a 96-well PCR plate.

(2) Operator(s) take the mosquito samples preserved at -80°C out of the freezer and arrange them on a 96-well tube rack according to the map. This step must be performed on ice to keep the samples cold.

(3) Operator(s) grind the mosquito samples using bead beating technique after adding 1 ml L-15 media to each mosquito sample.

(4) Operator(s) extract total RNA from mosquito samples using nucleic acid isolation techniques. Operator(s) may use nucleic isolation kits and automated equipment to achieve identical or better yield of nucleic acids.

(5) The RNA isolates can be utilized immediately for RT-PCR to amplify RNA segment of arboviruses or can be stored at -80°C. Operator(s) must plan in advance so that total RNA isolation and RT-PCR can be completed within a few days. The total RNA isolation and RT-PCR for a set of samples cannot be separated by longer than 3 days.

(6) Operator(s) try every effort to avoid repeated freezing and thawing of isolated RNA.

(7) Operator must include positive and negative controls in every RT-PCR run. The positive control will consist of total RNA isolated from a reference virus stock. The

negative control is PCR mix containing nuclease-free water in the place of target nucleic acids.

(8) Products from RT-PCR can be stored in 4°C until gel electrophoreses.

(9) For gel electrophoreses, operator(s) run a 5 µl aliquot of RT-PCR product on 2% agarose gel for pre-determined time at a pre-determined voltage.

(10) Operator(s) stain the gel using 0.5 µg/ml Ethidium bromide solution for photo imaging.

(11) Operator(s) must document the photo image of the gel for analysis.

(12) Operator(s) must update the datasheet submitted by NEON facilities by indicating samples that are positive for any arbovirus category of interest.

7. FORMS/TEMPLATES TO BE USED

This procedure requires datasheet submitted by NEON facilities.

8. INTERNAL AND EXTERNAL REFERENCES

8.1 Internal References

Not applicable.

8.2 External References

Not applicable.

9. CHANGE HISTORY

SOP no.	Effective Date	Significant Changes	Previous SOP no.
6	**8/15/2014**	**Initial SOP**	**New**
6	**2/2/2015**	**Revised to meet requirements from NEON**	**6**

SOP Number **7**

SOP Title **Secondary Analytical Methods**

	NAME	TITLE	SIGNATURE	DATE
Author	**Chang-Hyun Kim**	**Lab specialist**		**8/15/2014**
Reviewer	**Ephantus J. Muturi**	**Director**		**8/15/2014**
Authoriser	**Ephantus J. Muturi**	**Director**		**8/15/2014**

Effective Date:	**8/15/2014**
Review Date:	**2/2/2015**

READ BY			
NAME	**TITLE**	**SIGNATURE**	**DATE**

1. PURPOSE

This procedure is to ensure the quality of secondary analytical methods used for pathogen testing.

2. INTRODUCTION

When mosquito pools are submitted to Medical Entomology Laboratory, INHS, UIUC for arbovirus testing, they are assayed in two steps: First, RT-PCR is used to identify the arbovirus down to the family level. Second, Sanger DNA sequencing is used to identify the virus species/ or strain.

3. SCOPE

This procedure should be followed for all mosquito pools that are positive after RT-PCR amplification for arboviruses.

4. DEFINITIONS

PCR purification: isolation of PCR product from a mixture of PCR primers, salts and DNA polymerase after RT-PCR.

Gel purification: isolation of PCR product from a gel after gel electrophoresis.

5. RESPONSIBILITIES

Operator(s) must comply with the requirements of Division of Research Safety, UIUC.

6. SPECIFIC PROCEDURE

(1) Operator(s) must determine RT-PCR positive samples that are to be sequenced for virus strain based on the results from the primary analytical methods.

(2) Operator(s) must create a layout that indicates location of mosquito samples on a 96-well PCR plate. If the number of samples is manageable, individual PCR tubes or PCR tube strips may be used instead of a 96-well PCR plate. If individual PCR tubes or PCR tube strips are used, operator(s) must label each tube and maintain the label information on record.

(3) Operator(s) take the total RNA from mosquito samples preserved at -80°C out of the freezer and arrange them on a 96-well tube rack according to the layout. This step must be performed on ice to keep the total RNA cold.

(4) Operator(s) run RT-PCR to amplify RNA segment of arboviruses from the total RNA.

(5) Operator(s) try every effort to avoid repeated freezing and thawing of isolated RNA.

(6) Operator must include a positive and a negative control in every RT-PCR run. The positive control will consist of total RNA isolated from a reference virus stock. The negative control is PCR mix containing nuclease-free water in the place of target nucleic acids.

(7) Products from RT-PCR can be stored in 4°C until gel electrophoreses.

(8) For gel electrophoreses, operator(s) run a 20 µl aliquot of RT-PCR product on 2% agarose gel for pre-determined time at a pre-determined voltage.

(9) Operator(s) stain the gel using 0.5 µg/ml Ethidium bromide solution for photo imaging.

(10) Operator(s) must document the photo image of the gel for analysis.

(11) If any discrepancy found between primary and secondary analytical methods, operator(s) must update the datasheet submitted by NEON facilities by indicating samples that are positive for any arbovirus category of interest.

(12) Operator(s) excise the DNA band from 2% agarose gel and perform gel purification.

(13) If the PCR primers are proven to generate a single product from RT-PCR, operator(s) may omit steps from (8) to (12) and perform PCR purification.

(14) Operator(s) must measure and record the DNA concentration of purified RT-PCR product.

(15) Operator(s) arrange DNA sequencing for the purified RT-PCR product. The task can be achieved by running Sanger DNA sequencing at Medical Entomology Laboratory or referring to external facilities that run Sanger DNA sequencing.

(16) The sequencing results are to be analysed by the Basic Local Alignment Search Tool (BLAST) (http://blast.ncbi.nlm.nih.gov/blast/Blast.cgi?PROGRAM=blastn&PAGE_TYPE=BlastSearch&LINK_LOC=blasthome)

(17) Operator(s) record the identification results on the datasheet submitted by NEON facilities.

7. FORMS/TEMPLATES TO BE USED

This procedure requires datasheet submitted by NEON facilities.

8. INTERNAL AND EXTERNAL REFERENCES

8.1 Internal References

Not applicable.

8.2 External References

Not applicable.

9. CHANGE HISTORY

SOP no.	Effective Date	Significant Changes	Previous SOP no.
7	8/15/2014	Initial SOP	New
7	2/2/2015	Revised to meet requirements from NEON	7

SOP Number **8**

SOP Title **QAQC fails**

	NAME	TITLE	SIGNATURE	DATE
Author	**Chang-Hyun Kim**	**Lab specialist**		**8/15/2014**
Reviewer	**Ephantus J. Muturi**	**Director**		**8/15/2014**
Authoriser	**Ephantus J. Muturi**	**Director**		**8/15/2014**

Effective Date:	**8/15/2014**
Review Date:	**2/2/2015**

READ BY			
NAME	**TITLE**	**SIGNATURE**	**DATE**

1. PURPOSE

This procedure is to ensure the quality of analytical methods used for pathogen testing.

2. INTRODUCTION

Analytical methods used for identification of arboviruses are not error proof due to limitations in the specificity and sensitivity of techniques. In order to maintain the quality results, it is necessary to use sample controls to detect errors in the testing protocol and to reanalyse samples when there is an error detected in the control samples.

3. SCOPE

This procedure should be followed when Medical Entomology Laboratory, INHS, UIUC detects out-of-control result(s) from analytical methods for pathogen testing.

4. DEFINITIONS

Not applicable

5. RESPONSIBILITIES

Operator(s) must comply with the requirements of Division of Research Safety, UIUC.

6. SPECIFIC PROCEDURE

(1) Sample data associated with a failed quality control are evaluated for the need to be reanalysed or qualified.

   a) Sample results associated with failed quality control, such as a false positive and a false negative are rejected. The samples associated with the failed quality control are re-run.

   b) Sample results associated with wrong virus identification are rejected. The samples associated with failed quality control are re-run using identical or alternative techniques. The quality of alternative techniques must be approved by Medical Entomology Laboratory.

(2) Unacceptable quality control results are documented, and if the evaluation requires cause analysis, the cause and solution are recorded.

(3) The analyst is responsible for initiating corrective actions and ensuring that exceedances of quality control acceptance criteria are documented and reported to the director of Medical Entomology Laboratory, INHS, UIUC.

(4) Correction may include re-isolation of total RNA and/or re-analysis without further assessment. Corrective actions start with assessment of the cause of the problem.

(5) Corrective actions are documented on the corrective actions form. Comments and/or data qualifiers are entered in the comment section of the sample analysis result and reviewed by the quality assurance officer.

(6) If incorrect data is detected after reporting to NEON, operator(s) must inform NEON immediately and provide NEON either correct data or explanation of unacceptable data. In the case re-run is impossible, operator(s) must arrange with NEON for sample re-submission.

7. FORMS/TEMPLATES TO BE USED

This procedure requires datasheet submitted by NEON facilities.

8. INTERNAL AND EXTERNAL REFERENCES

8.1 Internal References

Not applicable.

8.2 External References

Not applicable.

9. CHANGE HISTORY

SOP no.	Effective Date	Significant Changes	Previous SOP no.
8	**8/15/2014**	**Initial SOP**	**New**
8	**2/2/2015**	**Revised to meet requirements from NEON**	**8**