CHEMBIO DIAGNOSTIC SYSTEMS, INC.
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1.0 PURPOSE

1.1 To define the standard receipt, inspection, testing, and disposition measures to be applied to each lot of Chembio HIV Rapid Test Control Pack lots (part number 60-9549-0) in conjunction with those procedures defined in B-260. The control pack is formulated to be used with HIV 1/2 STAT-PAK®

2.0 RAW MATERIAL DESCRIPTION

2.1	Name of Material:	Chembio HIV Rapid Test Control Pack
2.2	Chembio Part Number:	60-9549-0
2.3	Approved Vendor(s):	(1) Primary: ZeptoMetrix (2) Secondary: Not applicable
2.4	Vendor Part Number:	K-CMB006
2.5	Contents and Packaging:	A control pack consists of 3 vials (each containing 0.25mL defibrinated human plasma); one each of HIV-1 reactive, HIV-2 reactive, and nonreactive; all vials enclosed in a molded two-piece plastic container, over wrapped with a plastic bag; product insert provided.
2.6	Shipping Requirements:	Overnight, refrigerated (i.e., control packs are packaged in insulated boxes with ice packs, up to 350 control packs per box.)
2.7	Standard Usage:	Used for Quality Control evaluation of diagnostic test kits designed for the detection of antibodies to Human Immunodeficiency Virus (HIV)
2.8	Storage Requirements:	Store controls packs refrigerated at 2-8°C (36-46°F)
2.9	Ancillary Documentation:	Product insert (CDS part number 10-6187-0)
2.10	Expiry Dating:	The expiration dating applied for each control pack lot is vendor assigned.

3.0 DEFINITIONS

3.1 Not Applicable

4.0 RESPONSIBILITY AND AUTHORITY

4.1 The QA Inspector assigned to the handling of incoming raw materials is responsible for assuring that all information required by this procedure is recorded and that all required testing is performed.

4.2 The QC Manager or delegate is responsible for the review and approval of QC test results for all incoming material.

4.3 The Quality Director or delegate is responsible for the overall review and disposition of all incoming material.

5.0 REFERENCES

5.1 B-129 Non-Conforming Product.

5.2 B-260 Incoming Inspection and Forward Traceability.

5.3 B-402 Quality Sampling Procedure.

5.4 C-363 Use of HIV Evaluation Scale for Single Path Lateral Flow Product Formats.

6.0 RECEIVING, INSPECTION, AND TESTING REQUIREMENTS

6.1 The control pack(s) are received as described in B-260. Controls are to be stored at 2-8°C.

6.1.1 **NOTE**: For each lot of Chembio HIV Rapid Test Control Packs manufactured by ZeptoMetrix, a minimum of 2 sample packs are to be evaluated as per this RMS prior to shipment of the full order quantity and will serve as the lot specific QC retains (Part 1). The sample packs are to be shipped to the Medford, NY shipping location, whereas the balance of the lot is to be shipped to the Hauppauge, NY warehouse upon approval of lot release (Part 2).

6.1.2 Document receipt as per B-260. Initiate the inspection process as outlined below and document all results on Form 1 "*Record of Inspection and Testing (Sample Control Pack)*".

6.2 **Part 1 Shipments**

6.2.1 For Steps A and B on Form 1, verify that the materials have been sent from the approved vendor(s), that the material supplied has the correct material identification number, and that the material has arrived refrigerated and in good condition.

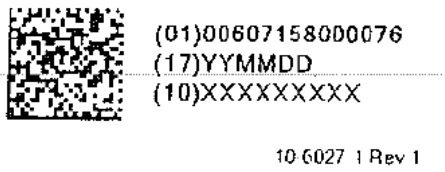
6.2.2 For Step C, verify that the quantity received is consistent with the quantity indicated by the vendor to have been shipped. Refer to the packing list. If the shipment quantity is incorrect, notify both the Receiving and Purchasing Departments.

6.2.3 For Step D, scan the barcodes that is present on the label using a calibrated scanner to verify that information present on the label matches with scanned information. Document calibration due date of the scanner used in comment section.

6.2.4 A Certificate of Analysis (COA) is required from the vendor for the specific control pack lot, in addition to a COA for each finished bulk lot used in the manufacture of the control pack lot as well as a Certificate of Conformance (COC) delineating the lots of material used in the control packs and the number shipped. These certificates must contain the information as presented on Form 3.

6.2.5 For Step E on Form 1, verify that the information presented on the COAs and COC is consistent with what is specified on Form 3. If a COA or COC is missing or incorrect, contact the vendor to obtain the required/corrected COA and/or COC. Materials may not be released without the specified COAs and COCs.

6.2.6 Referring to the label specifications found in the Quality Master Label Book, perform a visual inspection of the labeled control pack(s) and vials. The control pack and vial labels must be in accordance with the following part specifications:

PART #	DESCRIPTION
10-6188-0	HIV1 Vial Label
10-6189-0	HIV2 Vial Label
10-6084-0	Nonreactive Control Vial Label
10-6190-0	HIV Rapid Test Control Pack Container Label
10-6085-1	HIV Rapid Test Control Pack Contents Label
10-6027-1	Stat-Pak HIV 1-2 Rapid Test Control Pack UDI (See example below) 

6.2.6.1 Inspect for correct test and general appearance. Labels should be legible, clean, applied straight and centered with no lifting edges. In addition, verify

that the vials and control pack(s) are intact, showing no evidence of leakage. Document the required information under Step F on Form 1.

6.2.6.2 For P/N 10-6027-1, UDI Label, scan the bar code into Microsoft Word, print out the scan, and verify against Master Label. Document the required information under Step F on Form 1

6.2.7 Referring to the Quality Master Document binder for inserts, perform a visual inspection of the inserts contained within the control packs. The insert used must be in accordance with the following part specification:

PART #	DESCRIPTION
10-6187-0	HIV Rapid Test Control Pack Product Insert

6.2.7.1 Document the required information under Step F on Form 1. If any result does not meet the acceptance criteria, notify the QA Manager, or designee, and generate a Quarantine Notice as per B-129.

6.2.8 Conduct the functional testing as defined in Section 7.0 and document the results as specified on Form 1 (Steps G through I). If any result does not meet the defined specification, notify the QC Manager, or designee, and generate a Quarantine Notice as per B-129.

6.2.8.1 Functional testing data for sample control packs must be documented on Page 1 of 2 and 2 of 2 of Form 1: "*Record of Inspection and Testing (Sample Control Pack)"*.

6.3 Part 2 Shipments:

6.3.1 Once the control packs have arrived at the receiving warehouse, Steps A through F on Form 2 "*Record of Inspection and Testing (Lot)*" will be executed.

6.3.2 For Steps A and B on Form 2, verify that the materials have been sent from the approved vendor(s), that the material supplied has the correct material identification number, and that the material has arrived refrigerated and in good condition.

6.3.3 For Step C on Form 2, verify that the quantity received is consistent with the quantity indicated by the vendor to have been shipped. Refer to the packing list. If the shipment quantity is incorrect, notify both the Receiving and Purchasing Departments.

6.3.4 For Step D, scan the barcodes that is present on the label using a calibrated scanner to verify that information present on the label matches with scanned information. Document calibration due date of the scanner used in comment section

6.3.5 A Certificate of Conformance (COC) is required for the control pack shipment delineating the lots of material used in the control packs and the number shipped. The certificate must contain the information as presented on Form 3.

6.3.5.1 For Step E on Form 2, verify that the information presented on the COC is consistent with what is specified on Form 3. If a COC is missing or incorrect,

contact the vendor to obtain the required/corrected COC. Materials may not be released for shipment to customers without the specified COC.

6.3.6 Based on the requirements defined in B-402, select the required number of shipped insulated boxes to open and select the number of control packs for visual inspection following an S-2 (AQL 1.0) sampling plan. Inspect the selected control packs from each box opened for the following:

6.3.6.1 Correct number of vials and control type in each pack.

6.3.6.2 Caps are secure on each vial with no evidence of leakage.

6.3.6.3 Correct cap coloring based on control type.

6.3.6.4 Correct text and general appearance of labels and insert(s).

6.3.6.4.1 All vial and outer container labels should be legible, clean, applied straight and centered with no lifting edges. The printed lot numbers must be correct.

6.3.6.4.2 Scan the required number of UDI labels into Microsoft Word. Print out the scans and verify against Master Label.

6.3.6.4.3 Product insert should have correct text and be free of smudges or other defects. The version used must be the current approved version.

6.3.6.5 General cleanliness of the packaged material and any foreign matter that may be present.

6.3.6.6 Document the results under Step F on Form 2. If any result does not meet the acceptance criteria, notify the QA Manager, or designee, and generate a Quarantine Notice as per B-129.

7.0 FUNCTIONAL TESTING REQUIREMENTS

7.1 The contents of the three vials contained within one of the sample packs received will be tested using one approved HIV 1/2 STAT-PAK lot and one approved SURE CHECK HIV 1/2 lot.

7.1.1 Mark the control pack used for testing with the date on which the vials were first opened.

7.1.2 Only one replicate is required for each control vial to be tested using each of the product formats specified. Conduct testing in accordance with the control pack and product specific insert(s) and determine line intensities using the HIV evaluation scale defined in C-363.

7.1.3 Document all functional testing results on Form 1 page 1 of 2 and 2 of 2.

7.1.4 The QC Manager, or designee, must review all results obtained.

7.2 Acceptance Criteria

7.2.1 The Nonreactive Control must yield a nonreactive test line result (N1 or N2 intensity) for at least twenty minutes from the time the test is initiated.

7.2.2 The HIV-1 and HIV-2 Reactive Controls must each yield a test line that is visible within fifteen minutes and that has a minimum intensity of 1.

7.2.3 The control line for each test conducted must be visible within fifteen minutes and must have a minimum intensity of 2.

8.0 MATERIAL DISPOSITION

8.1 **Part 1 Shipment**: If all results for the visual inspection and functional testing are satisfactory, the Quality Director, or designee, will approve/release the subject control pack lot by signing the required section(s) on Form 1.

8.1.1 Once approval has been granted, the sample control packs will be labeled with standard release labeling and stored as QC retains in the designated 2-8°C refrigerator. The expiration dating applied for each control pack lot is vendor assigned.

8.1.2 In addition, the vendor and other Chembio personnel indicated must be notified of the approval to release the control pack lot for shipment from ZeptoMetrix to Chembio.

8.1.2.1 Send E-mail to: Antylia/ ZeptoMetrix.

8.1.2.2 Send E-mail to Warehouse Supervisor (Chembio).

8.1.2.3 Send E-mail to Senior Director, Operations Planning and Logistics (Chembio).

8.1.2.4 Send E-mail to Director of Client Services (Chembio).

8.2 **Part 2 Shipment**: If all results for the visual inspection are satisfactory, the Quality Director, or designee, will approve/release the subject control pack lot for distribution to customers by signing the required section(s) on Form 2.

8.2.1 Once approval has been granted, each outer storage box container the individual control packs will be labeled with standard release labeling and stored in the designated 2-8°C walk-in refrigerator in the Hauppauge warehouse. The expiration dating applied for each control pack lot is vendor assigned.

8.3 File Form 1 and Form 2 with the associated COA's and the COC in the Raw Material file storage area.

8.4 If any of the above stated release criteria are not met, the control pack lot is to be quarantined as per B-129, and the material will be dispositioned accordingly.

Document History Record

Date	Rev	Description of Change
5-Jun-14	1	CCR # 2507; Initial release.
13-Dec-21	2	CCR # CDS-21-387; Company Logo Updated Formatting throughout the document Section 2.10 added Expiry Dating Section 6.1.1 and 8.2.1 Revised from “Holbrook” to “Hauppauge” Section 6.1.2 added Title of Form 1 Section 6.2.3 and 6.3.4 added need to scan barcode during QA inspection. Same done for the Form 1 and Form 2 Added Section 6.2.8.1 and 7.1.3 Results of function testing to be documented on page 1 of 22 and 2 of 2 of Form 1. 6.3.1 revised “Holbrook” to “Receiving”. Section 6.3.6.6 added “*Document the results under step F on Form 2. If any results does not meet criteria, notify the QA Manager, or Designee, and generate a Quarantine Notice as per B-129.*” Section 8.1 and 8.2 Clarified by Part 1 shipment and part 2 shipment.
21-Apr-22	3	CCR # CDS-21-393 Section 6.2.6 Added UDI Label Chembio part number and picture of the Label. Section 6.3.6.4.2 Added Scan the required number of UDI labels into Microsoft Word. Print out the scans and verify against Master Label.

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Form 1: Record of Inspection and Testing (Sample Control Pack)

(Page 1 of 2)

Sample Control Pack(s) Inspected By / Date	Test Results Reviewed By / Date	CDS Lot Number	PO Number
		Vendor Lot Number	Expiration Date

Step	Inspection Criteria		Pass	Fail	Comments
A	Approved vendor and vendor item number ZeptoMetrix, Item No. K-CMB006				
B	Controls arrived refrigerated (ice packs) and in good condition.				
C	Shipment Quantity verified: _____ / _____ (Qty. Received) (Qty. on Packing Slip)				
D	UDI Label (Barcodes) on control pack labels were scanned and information matches with information on labels. **Scanner Calibration Due Date**				**Due Date**: _____
E	Vendor COAs and COC attached for the control pack lot. Information is correct, and all results meet the defined specifications.				
F	**Visual Inspection**				
	Each boxed sample contains one nonreactive control, one HIV 1 reactive control and one HIV 2 reactive control.				
	Control caps are on tight and do not appear to have leaked.				
	Correct control cap color used.	Nonreactive Control = White HIV 1 Reactive Control = Red HIV 2 Reactive Control = Green			
	Correct labels have been used and are clean and applied properly.				
	Control vials and boxes are clean and not damaged.				
	Correct product insert has been provided: _____ (Part #, Revision)				
Functional Testing of Sample Packs Only					
G	Functional testing for Nonreactive Control: Vial marked "Nonreactive Control" must produce a nonreactive result for twenty minutes				
H	Functional testing for HIV 1 Reactive Control: Vial marked "HIV 1 Reactive Control" must produce a test line within fifteen minutes that has a minimal final intensity of 1				
I	Functional testing for HIV 2 Reactive Control: Vial marked "HIV 2 Reactive Control" must produce a test line within fifteen minutes that has a minimal final intensity of 1				

Comments:

_____

_____

MATERIAL DISPOSITION:

Lot Approved / Rejected by: _____ Date: _____

(Quality Director or delegate)

Quarantine #: _____ (if applicable) Date ZeptoMetrix Notified of Disposition: _____

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Form 1: Record of Inspection and Testing (Sample Control Pack)

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Lot Number of HIV Rapid Test Control Pack Tested: _____ / _____
(CDS L/N) (Vendor L/N)

Expiration Date: _____

Reactive results are to be recorded as time for test line to appear / intensity at fifteen minutes. Non-reactive results may be recorded as "negative". Acceptance criteria defined in Section 7.2.

Control Sample:	**HIV Negative**	**HIV 1 Reactive**	**HIV 2 Reactive**
Lot number of individual control: (Vendor assigned)			
Result on HIV 1/2 STAT-PAK® Lot: _____ Exp: _____		/	/
Result on Sure Check HIV 1/2 Lot: _____ Exp: _____		/	/
Control line(s) appeared within 15 minutes of initiating test(s), each with an intensity of ≥ 2:	Yes / No	Yes / No	Yes / No
Final Results:	Pass / Fail	Pass / Fail	Pass / Fail

Comments: _____

_____

Functional testing performed by: _____ Date: _____

Reviewed by: _____ Date: _____
Quality Control

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Form 2: Record of Inspection and Testing (Lot)

Control Pack(s) Inspected By / Date	CDS Lot Number	PO Number
	Vendor Lot Number	Expiration Date

Step	Inspection Criteria				Pass	Fail	Comments
A	Approved vendor and vendor item number ZeptoMetrix, Item No. K-CMB006						
B	Controls arrived refrigerated (ice packs) and in good condition.						
C	Shipment Quantity verified: _____ / _____ (Qty. Received) (Qty. on Packing Slip)						
D	Barcodes on control pack labels were scanned and information matches with information on labels. **Scanner Calibration Due Date**						**Due Date**: _____
E	Vendor COC attached for the control pack lot. Information is correct, and all results meet the defined specifications.						
F	**Visual Inspection**	**# Inspected / # Acceptable**					
	Correct version of both outer labels was used; lot number is correct on front label.	/					
	Each control pack contains one nonreactive control, one HIV 1 reactive control and one HIV 2 reactive control.	/					
	Control vials and boxes are clean and not damaged.	/					
	Correct product insert has been provided: _____ (Part #, Revision)	/					
	Control caps are on tight and do not appear to have leaked.	NRC: /	HIV 1 RC: /	HIV 2 RC: /			
	Correct control cap color used Nonreactive Control = White HIV 1 Reactive Control = Red HIV 2 Reactive Control = Green	/	/	/			
	Correct vial labels have been used and are clean and applied properly.	/	/	/			
	Correct lot numbers are present on each vial label.	/	/	/			

Comments: _____

_____

MATERIAL DISPOSITION:

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Lot Approved / Rejected by: _____ Date: _____
(Quality Director or delegate)

Quarantine #: _____ (if applicable)

Form 3: Sample Certificates
(Page 1 of 5)

Certificate of Analysis

Finished Bulk		*Specification*
Product Name:	HIV Negative Control Bulk	
Supplier Code:	9006C	
Lot Number:	XXXX-XXX-XXXXX	
Donor Stock Titer:	Neat	Neat
Date of Manufacture:	MM/YYYY	
Expiration Date:	MM/YYYY	24 *months from date of mfg*
Volume:	300 mL	
Storage:	<-10°C	
Genetic Systems rLAV:		
Neat	S/Co TBD	*S/Co <1.0*
Genetic Systems HIV II EIA:		
Neat	S/Co TBD	*S/Co <1.0*
Sure Check HIV 1/2 or Clearview HIV1/2:		
Neat: TBD	TBD	*Negative*
Stat Pak HIV Rapid Test:		
Neat: TBD/TBD/TBD	TBD	*Negative*
Bioburden: (Thioglycollate broth incubated 24-72 hrs.)	No Growth	*No Growth*
Heat Treatment:	56 (°C) for 60 (Min.)	*56±1°C for 60±5 Min.*

Donor Pool Stock Testing		
* HBsAg:	Negative	*Negative*
HBc IgM:	Negative	*Negative*
* Anti-HCV:	Negative	*Negative*
HIV(RNA) /p24:	Negative	*Negative*
* HTLV I/II Ab:	Negative	*Negative*
Syphilis (RPR):	Negative	*Negative*

** Must use FDA approved kits*

Product Description: Chembio HIV Negative Control Bulk is manufactured specifically for use with Chembio HIV Rapid Assays. This bulk material may be repackaged for sale.

Inactivation: Heat Inactivation Procedure was carried out on this lot of Chembio HIV Negative Control Bulk

Intended Use: Chembio HIV Negative Control Bulk is for use in further manufacturing or for research use only. Not for use as an *in vitro* diagnostic. This material is not intended for use in the manufacturing or processing of injectable products subject to licensure under section 351 of the Public Health Service Act or for any other product intended for administration to humans. HIV Negative Control Bulk has been treated by a method validated to be effective for the inactivation of HIV. No method can be guaranteed 100% effective. This material should be handled as if capable of transmitting infectious agents. **Use Universal Precautions.**

Quality Statement: The undersigned has reviewed the Quality Control test results and found this lot to meet specifications. They certify that the results reported in this Certificate of Analysis accurately reflect the data contained in the Chembio HIV Negative Control Bulk batch production and testing records.

_____ _____
Authorized Personnel Date

Form 3: Sample Certificates
(Page 2 of 5)

Certificate of Analysis

Finished Bulk		*Specification*
Product Name:	HIV-1 Positive Control Bulk	
Supplier Code:	9006D	
Lot Number:	XXXX-XXX-XXXXX	
Donor Stock Titer	1:8	1:8
Date of Manufacture:	MM/YYYY	
Expiration Date:	MM/YYYY	24 *months from date of mfg*
Volume:	300 mL	
Storage:	<-10°C	
Sure Check HIV 1/2 or Clearview HIV1/2:		
Neat: TBD	TBD	*Positive*
Stat Pak HIV Rapid Test:		
Neat: TBD/TBD/TBD	TBD	*Positive*
Bioburden:(Thioglycollate broth incubated 24-72 hrs.)	No Growth	*No Growth*
Heat Treatment:	56(°C) for 60 (Min.)	*56±1°C for 60±5 Min.*

Donor Pool Stock Testing		
** HBsAg:	Negative	*Negative*
HBc IgM:	Negative	*Negative*
** Anti-HCV:	Negative	*Negative*
** HTLV I/II Ab:	Negative	*Negative*
Syphilis (RPR):	Negative	*Negative*

*** Must use FDA approved kits*

Product Description: Chembio HIV-1 Positive Control Bulk is manufactured specifically for use with Chembio HIV Rapid Assays. This bulk material may be repackaged for sale.

Inactivation: Heat Inactivation Procedure was carried out on this lot of Chembio HIV-1 Positive Control Bulk

Intended Use: Chembio HIV-1 Positive Control Bulk is for use in further manufacturing or for research use only. Not for use as an *in vitro* diagnostic. This material is not intended for use in the manufacturing or processing of injectable products subject to licensure under section 351 of the Public Health Service Act or for any other product intended for administration to humans. HIV-1 Positive Control Bulk has been treated by a method validated to be effective for the inactivation of HIV. No method can be guaranteed 100% effective. This material should be handled as if capable of transmitting infectious agents. **Use Universal Precautions.**

Quality Statement: The undersigned has reviewed the Quality Control test results and found this lot to meet specifications. They certify that the results reported in this Certificate of Analysis accurately reflect the data contained in the Chembio HIV-1 Positive Control Bulk batch production and testing records.

_____ _____
Authorized Personnel Date

Form 3: Sample Certificates
(Page 3 of 5)

Certificate of Analysis

Finished Bulk		*Specification*
Product Name:	HIV-2 Positive Control Bulk	
Supplier Code:	9006E	
Lot Number:	XXXX-XXX-XXXXX	
Donor Stock Titer	1:8	1:8
Date of Manufacture:	MM/YYYY	
Expiration Date:	MM/YYYY	24 *months from date of mfg*
Volume:	300 mL	
Storage:	<-10°C	
Sure Check HIV 1/2 or Clearview HIV1/2:		
Neat: TBD	TBD	*Positive*
Stat Pak HIV Rapid Test:		
Neat: TBD/TBD/TBD	TBD	*Positive*
Bioburden:(Thioglycollate broth incubated 24-72 hrs.)	No Growth	*No Growth*
Heat Treatment:	56 (°C) for 60 (Min.)	*56±1°C for 60±5 Min.*

Donor Pool Stock Testing		
** HBsAg:	Negative	*Negative*
HBc IgM:	Negative	*Negative*
** Anti-HCV:	Negative	*Negative*
** HTLV I/II Ab:	Negative	*Negative*
Syphilis (RPR):	Negative	*Negative*

*** Must use FDA approved kits*

Product Description: Chembio HIV-2 Positive Control Bulk is manufactured specifically for use with Chembio HIV Rapid Assays. This bulk material may be repackaged for sale.

Inactivation: Heat Inactivation Procedure was carried out on this lot of Chembio HIV-2 Positive Control Bulk

Intended Use: Chembio HIV-2 Positive Control Bulk is for use in further manufacturing or for research use only. Not for use as an *in vitro* diagnostic. This material is not intended for use in the manufacturing or processing of injectable products subject to licensure under section 351 of the Public Health Service Act or for any other product intended for administration to humans. HIV-2 Positive Control Bulk has been treated by a method validated to be effective for the inactivation of HIV. No method can be guaranteed 100% effective. This material should be handled as if capable of transmitting infectious agents. **Use Universal Precautions.**

Quality Statement: The undersigned has reviewed the Quality Control test results and found this lot to meet specifications. They certify that the results reported in this Certificate of Analysis accurately reflect the data contained in the Chembio HIV-2 Positive Control Bulk batch production and testing records.

Authorized Personnel _____ Date _____

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Form 3: Sample Certificates
(Page 4 of 5)

Certificate of Analysis

Finished Goods		*Specification*
Product Name:	HIV Rapid Test Control Pack	
Supplier Part Number:	K-CMB006	
Chembio Part Number:	60-9549-0	
Lot Number:	XXXXXXXXX	
Date of Manufacture:	YYYY/MM	
Expiration Date:	YYYY/MM	24 *months from date of mfg*
Storage:	2-8°C	
HIV 1/2 NEGATIVE CONTROL (XXXX-XXX-XXXXX)		
Fill Volume:	0.25 mL	
HIV 1/2 Kit:	S/Co <TBD	*S/Co <1*
HIV-2 Kit:	S/Co <TBD	*S/Co <1*
Sure Check HIV 1/2 or Clearview HIV 1/2:		
TBD	TBD	*Negative*
Stat Pak HIV Rapid Test:		
TBD/TBD/TBD	TBD	*Negative*
Heat Treatment:	56°C for 60 Min.	*56±1°C for 60±5 Min.*
Bioburden	No Growth	*No Growth*
HIV-1 POSTIVE CONTROL (XXX-XXX-XXXXX)		
Fill Volume:	0.25 mL	
Sure Check HIV 1/2 or Clearview HIV 1/2:		
TBD	TBD	*Positive*
Stat Pak HIV Rapid Test:		
TBD/TBD/TBD	TBD	*Positive*
Heat Treatment:	56°C for 60 Min.	*56±1°C for 60±5 Min.*
Bioburden	No Growth	*No Growth*
HIV-2 POSITIVE CONTROL (XXXX-XXX-XXXXX)		
Fill Volume:	0.25 mL	
Sure Check HIV 1/2 or Clearview HIV 1/2:		
TBD	TBD	*Positive*
Stat Pak HIV Rapid Test:		
TBD/TBD/TBD	TBD	*Positive*
Heat Treatment:	56°C for 60 Min.	*56±1°C for 60±5 Min.*
Bioburden	No Growth	*No Growth*
Donor Pool Stock Testing		
HBsAg:	Negative	*Negative*
HBc IgM:	Negative	*Negative*
Anti-HCV:	Negative	*Negative*
HTLV I/II Ab:	Negative	*Negative*
Syphilis (RPR):	Negative	*Negative*

Product Description: HIV Rapid Test Control Pack (K-CMB006) is manufactured specifically for use with Chembio HIV Rapid Assays. Each Control Pack contains 1 vial Negative Control Sera, 1 vial HIV-1 Positive Control Sera and 1 vial HIV-2 Positive Control Sera.

Inactivation: Heat Inactivation Procedure was carried out on each member of the HIV Rapid Test Control Pack (K-CMB006). This method is validated to be effective for the inactivation of HIV. No method can be guaranteed 100% effective. This material should be handled as if capable of transmitting infectious agents. **Use Universal Precautions.**

Quality Statement: The undersigned has reviewed the Quality Control test results and found this lot to meet specifications. They certify that the results reported in this Certificate of Analysis accurately reflect the data contained in the HIV Rapid Test Control Pack (K-CMB006) batch production and testing records.

Authorized Personnel _____ Date _____

April 1, 2014 Rev00

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Form 3: Sample Certificates
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Certificate of Conformance

Product Name:	HIV Rapid Test Control Pack
Supplier Code:	K-CMB006
Chembio Part Number:	60-9549-0
Quantity Packaged:	N,NNN Control Packs
Kit Lot Number:	XXXXXXXXX
Kit Expiration Date:	YYYY,MM
HIV 1/2 Negative Control Lot Number:	XXXX-XXX-XXXXX
Expiration Date:	YYYY,MM
HIV-1 Positive Control Lot Number:	XXXX-XXX-XXXXX
Expiration Date:	YYYY,MM
HIV-2 Positive Control: Lot Number:	XXXX-XXX-XXXXX
Expiration Date:	YYYY,MM

With this document, the manufacturer certifies this product conforms to the latest specifications and was manufactured in accordance with the requirements of 21 CFR Part 820 FDA Quality System Regulation (cGMP).

_____ _____
Authorized Personnel Date