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Prepared by QA Committee	Criteria	
Issued by: Laboratory Manager	Revision Date:1/15/2024	
Approved by Laboratory Director:	Next Review Date: 11/15/2025	
Microbiologist-in-Chief		

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Introduction

External Controls are samples external to tests kit provided with known expected results to assess the accuracy of a test. External controls are run according to individual test procedure but often tested on new test kit lot numbers, shipments or after major maintenance or deviation from standard conditions occurs.

Procedure

Use the chart below to determine which serology external controls to run by analyte. **Class must be specified when order is placed.

Select Packaging	Product	Class	Analyte, Test Method
VIROTROL I Cat # 00101	1 x 5ml 10 x 4 ml	F	HBsAg, Abbott Architect Anti-HIV-1, Abbott Architect Anti-HTLV-I, Abbott Architect Anti-HBcore, Abbott Architect Anti-HCV, Abbott Architect Anti-CMV Total EIA, Immucor
VIROTROL II Cat # 00104	1 x 5 ml	B+	Anti-HBs, Abbott Architect Anti-HAV, Abbott Architec
VIROTROL III	1 x 5 ml	В	Anti-HBc IgM, Abbott Architect Anti-HAV IgM, Abbott Architect
VIROTROL HIV-2 Cat # 00105C	1 x 5 ml	С	HIV-2 Abbott Architect
VIROTROL HIV-1 Ag Cat # 00108A	1 x 5 ml	A	HIV-1 (P24) Ag Abbott Architect

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VIROTROL SYPHILIS Cat# 00071X	1 x 5 ml	N/A	Syphilis TP Ab Abbott Architect
VIROCLEAR Cat # 00112	1 0x 4 ml	N/A	All(except Rubella IgG)
VIROToRCH Cat# 000109	1 x 5 ml \$ 300.00	N/A	CMV IgG Abbott Architect
VIROToRCH-M Cat# 000117	1 x 5 ml \$ 438.00	N/A	CMV IgM Abbott Architect

Related Documents

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Record of Edited Revisions

Manual Section Name: External Control Selection Criteria

Page Number / Item	Date of Revision	Signature of Approval
Transferred and updated from Architect Manual, Policy #	2017.02.16	Dr. T. Mazzulli
MI/SER/ARCHIv05		
Annual Review	May 17, 2017	Dr. T. Mazzulli
Corrected Cat number and class for HIV controls		
Annual Review	May 17, 2018	Dr. T. Mazzulli
Annual Review	May 17, 2019	Dr. T. Mazzulli
Annual Review	May 17, 2020	Dr. T. Mazzulli

Full document review included in all updates. Bi-annual review conducted when no revision had been made within 2 years.

Page Number / Item	Date of Revision	Edited by:
Minor formatting change	April 12, 2021	Jessica Bourke
Biennial Review with no change	February 27, 2023	Jamaal Pratt
Minor formatting change	November 22, 2023	Jamaal Pratt

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