

Molecular Diagnostics Specimen Selection Guide

Overview

Focus Diagnostics offers a growing number of molecular-based assays for the detection, quantitation, and genomic analysis of different infectious pathogens. Focus is continually expanding its molecular diagnostics test menu to provide more advanced tools for disease management, as described in the medical and scientific literature. New assays are developed for emerging pathogens and also for known pathogens, where more sensitive detection or specific genomic information is desired.

At Focus Diagnostics, our reputation stands on the quality of our test results. We therefore go the extra mile to provide a test result that is as accurate as possible. In addition to positive and negative target amplification controls, Focus Diagnostics incorporates additional quality controls. An internal amplification control is evaluated for each specimen that verifies the successful DNA/RNA extraction and amplification from the patient's specimen. Each assay run includes controls to detect possible contamination not only during amplification and detection, but also during the specimen processing step. These controls, used in conjunction with physical containment barriers, minimize false-positive and false-negative results.

PCR

For clinical studies and diagnostic use, PCR testing is considered by many to be the gold standard. In an effort to provide test results in as timely a manner as possible, Focus Diagnostics utilizes Real-Time PCR technology in many of its molecular assays to decrease test turn-around-time. Real-Time PCR combines the amplification and detection steps of the molecular assay to provide faster results with greater standardization.

Test Request Information

Focus' Molecular Diagnostics Department requests that as much information as possible be provided with each specimen. This should include specimen source, patient age and date of birth, and physician name.

Collection Time, Transportation and Storage Guidelines

Specimens should ideally be collected in the acute phase of infection and transported to the laboratory as soon as possible, usually 24 hours post collection. The charts included in this section describe optimal collection and transport procedures by organism. This information serves as a guide only. Please do not hesitate to call Focus' Client Service Representatives or Molecular Diagnostics Department for further details regarding the selection, collection and transport of specimens.

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Refer to individual assays for exact specimen requirements and transport temperatures.

Assay	Validated Specimens	Unacceptable Specimens¹
Adenovirus DNA, Qualitative and Quantitative	Whole blood or Plasma (EDTA, ACD), Serum, CSF, Urine, BAL, Sputum, Respiratory swab in transport media	Calcium alginate swabs, Tissue unacceptable for quantitation.
Anaplasma phagocytophilum DNA	Whole blood (EDTA, ACD), Ticks	
Aspergillus DNA	Whole blood (EDTA, ACD), BAL, Serum, Tissue	
Atypical Pneumonia Panel <i>Panel includes:</i> Chlamydia Legionella Mycoplasma	BAL/wash, Sputum, Respiratory specimen in transport media	Calcium alginate swabs
Avian Influenza Virus H5 Gene RNA	NPA/wash, NP/throat swab; Sputum	Tissue
Babesia microti DNA	Whole Blood (ACD, EDTA), Ticks	
Bartonella DNA	Whole Blood (ACD, EDTA), Tissue	
BK Virus DNA, Qualitative and Quantitative BK and JC Virus DNA	Whole blood and Plasma (EDTA, ACD), Urine, Serum, CSF Whole blood and Plasma (EDTA, ACD), Urine, Serum, Plasma, CSF	Tissue unacceptable for Quantitation
Bordetella pertussis/ parapertussis DNA	NPA/wash, Nasal swab	Calcium alginate swabs
Borrelia burgdorferi DNA	Whole blood, (EDTA, ACD), Tick; Synovial fluid, CSF, Urine	
Chlamydia pneumoniae DNA	BAL/wash, Sputum, Respiratory specimen in transport media	Calcium alginate swabs
Clostridium difficile (Toxigenic) DNA	Stool	
Cytomegalovirus DNA, Qualitative and Quantitative	Whole blood, Plasma, Serum, CSF, Amniotic fluid, Urine, Tissue	Tissue unacceptable for quantitation
Cytomegalovirus Genotyping	Whole blood and Plasma (EDTA, ACD), CSF, BAL, Buffy coat, Cultured cells, Specimen in transport media	All other specimens
Coronavirus (Non-SARS) RNA	NPA, BAL, NP/Throat swab	Calcium alginate swabs, Tissue
Dengue Virus RNA	Serum	Tissue

1. All specimens (Whole Blood, Plasma, Bone Marrow) using Heparin as the anticoagulant are unacceptable.

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Ehrlichia chaffeensis DNA	Whole blood, Tick	
Ehrlichia ewingii DNA	Whole blood, Tick	
Enterovirus RNA	CSF, Plasma (EDTA, PPT, ACD), Stool, Throat/rectal swab	Calcium alginate swabs, Tissue
Epstein-Barr Virus DNA, Qualitative and Quantitative	Whole blood and Plasma (EDTA, ACD), Serum, Bone marrow, CSF, Tissue	Tissue unacceptable for quantitation
Hepatitis B Virus DNA, Qualitative and Quantitative	Serum, Plasma (EDTA, PPT, ACD)	Tissue and Whole blood are unacceptable for quantitation
Hepatitis C Virus Genotyping	Plasma (EDTA, PPT, ACD), Serum	All other specimens
Hepatitis C Virus RNA, Qualitative and Quantitative	Plasma (EDTA, PPT, ACD), Serum	All other specimens
Hepatitis D Virus RNA	Serum	Tissue
Hepatitis G Virus RNA	Serum, Plasma (EDTA, PPT, ACD)	Tissue
Herpes Simplex Virus 1/2 DNA, Qualitative and Quantitative	CSF, Serum, Tissue, Swab, Pleural fluid, Pericardial fluid, Amniotic fluid, Vitreous fluid	Tissue unacceptable for quantitation
Herpesvirus-6 DNA, Qualitative and Quantitative	Whole blood and Plasma (EDTA, ACD), Serum, CSF	Tissue unacceptable for quantitation
Herpesvirus-7 DNA, Quantitative	Whole blood and Plasma (EDTA, ACD), Serum	Tissue
Herpesvirus-8 DNA, Qualitative and Quantitative	Whole blood and Plasma (EDTA, ACD), Serum	Tissue unacceptable for quantitation
Histoplasma capsulatum DNA	Whole blood (EDTA, ACD), BAL, CSF, Urine, Tissue	
HIV-1 Proviral DNA	Whole blood (EDTA, ACD)	All other specimens
HIV-1 Genotype	Plasma (EDTA, PPT, ACD), Serum	All other specimens
HIV-1 RNA, Quantitative	Plasma (EDTA, PPT, ACD)	All other specimens
HIV-2 DNA/RNA	Whole blood (EDTA, ACD)	
HTLV I/II DNA	Whole blood (EDTA, ACD)	All other specimens
Human metapneumovirus RNA	NP aspirate or swab, BAL	Tissue, Calcium alginate swabs

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Influenza Virus A/B RNA	BAL/wash, Sputum, Respiratory specimen in transport media	Tissue, Calcium alginate swabs
JC Virus DNA, Qualitative and Quantitative	CSF, Plasma (EDTA, PPT, ACD), Serum, Urine	Tissue unacceptable for quantitation
Legionella pneumophila DNA	BAL/wash, Sputum, Respiratory specimen in transport media	Calcium alginate swabs
Mycobacterium tuberculosis (MTB) DNA	Respiratory specimen, CSF or tissue	Whole blood, Serum, Plasma, Bone marrow, Bactec bottles, Urine
Mycoplasma pneumoniae DNA	BAL/wash, Sputum, Respiratory specimen in transport media	Calcium alginate swabs
Norovirus RNA	Stool	Tissue
Parainfluenza Virus RNA	BAL/wash, Sputum, Respiratory specimen in transport media	Tissue, Calcium alginate swabs
Parechovirus RNA	CSF, Stool	Tissue
Parvovirus B19 DNA Qualitative and Quantitative	Whole blood, Plasma, Serum, Amniotic fluid, Tissue, Bone Marrow	Tissue unacceptable for quantitation
Respiratory Syncytial Virus RNA	BAL/wash, Sputum, Respiratory specimen in transport media	Tissue, Calcium alginate swabs
Respiratory Virus Panel <i>Panel includes:</i> Influenza Virus A/B RNA Respiratory Syncytial Virus RNA Parainfluenza Virus RNA Adenovirus DNA	BAL/wash, Sputum, Respiratory specimen in transport media	Tissue, Calcium alginate swabs
Rhinovirus RNA	NPA or swab, BAL	Tissue
Rickettsia rickettsii	Whole blood (EDTA, ACD), Tick	
SARS Coronavirus RNA	NPA/Swab, BAL, Sputum, Rectal swab	Tissue, Calcium alginate swabs

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<i>Assay</i>	<i>Validated Specimens</i>	<i>Unacceptable Specimens</i>
Tick Borne Disease Panel <i>Panel includes:</i> Anaplasma phagocytophilum DNA Babesia microti DNA Borrelia burgdorferi DNA Erlichia chaffeensis DNA	Whole blood (EDTA, ACD), Tick	
Toxoplasma gondii DNA, Qualitative and Quantitative	Amniotic fluid, CSF, Whole blood and Plasma (EDTA, ACD), Serum, Vitreous fluid, Tissue	Tissue unacceptable for quantitation
Tropheryma whipplei DNA	Whole blood (EDTA, ACD), CSF, Tissue	
Varicella Zoster Virus DNA, Qualitative and Quantitative	Whole blood (EDTA, ACD), CSF, Bronchial Wash/Brush, Swab in transport media, Tissue	Calcium alginate swabs, Tissue unacceptable for quantitation
West Nile Virus RNA	CSF, Plasma (EDTA, PPT, ACD), Serum	Tissue