



QUIDEL®



QuickVue®
Rapid Diagnostics

PRODUCT CATALOG



Quidel is a leading manufacturer of diagnostic healthcare solutions serving to enhance the health and well-being of people around the globe through the development of diagnostic solutions that can lead to improved patient outcomes and provide economic benefits to the healthcare system.

Our product base and technology platforms have continued to expand through internal development and acquisitions of other products and technologies allowing for a core competency that includes:

- Immuno and molecular assay development
- Automated manufacturing lateral flow (LF) technologies
- Direct fluorescent antibodies (DFA) production
- Monoclonal antibody characterization



Rapid Point-of-Care (POC) testing for certain diseases has become a more accepted aide to centralized testing. POC tests are primarily performed in non-institutional settings such as physicians' offices, as well as specific areas of the hospital including emergency rooms, and at the patient's bedside. To meet this need, Quidel developed the QuickVue line of rapid lateral flow tests that produce accurate results in minutes, allowing for faster diagnosis and treatment.

Quidel has manufactured the QuickVue® brand line of products for hospital and physician office labs for over 30 years, under a Quality Management System certified to ISO 13485. Focusing in the areas of infectious diseases and women's health, these products have continued to deliver quality results with a variety of formats well suited for different POC needs.

QuickVue®

QuickVue+

QuickVue In-Line® QuickVue®TLI

Rapid POC testing for certain diseases has become a more accepted aide to centralized testing.

Rapid Diagnostics

For Point of Care Testing

Easy to use, fast and accurate, QuickVue is used with patients in acute care facilities and physicians offices, QuickVue®, QuickVue+® and QuickVue In-Line® tests aid in the diagnosis of these disease states and conditions.

QuickVue Influenza A+B Test

Immunoassay for the differential detection of influenza type A and type B from nasal swab and nasopharyngeal swab (NPS) specimens, direct and VTM.

- Results in 10 minutes or less
- 3 steps (nasopharyngeal swab, NPS)
- Less than 30 seconds hands-on time
- 1 reagent
- High specificity for influenza
- Not affected by variations of seasonal influenza strains
- CLIA waived



Catalog #	Qty	Description
20183	25 tests	QuickVue Influenza A+B Test Kit
20103	25 swabs	Nasal Swab Pack
20171	25 swabs	Influenza Nasal Swab Transport Tubes
20171	100 swabs	Nasopharyngeal Swab Pack

QuickVue SARS Antigen Test

Immunoassay for the qualitative detection of SARS-CoV-2 antigen in anterior nares specimens.

- Results in 10 minutes
- 96.6% Positive Percent Agreement
- 99.3% Negative Percent Agreement
- 1 reagent
- No age restriction
- Available with Emergency Use Authorization only



Catalog #	Qty	Description
20387	25 tests	QuickVue SARS Antigen Test Kit

QuickVue+ Mononucleosis Test

Immunoassay for the rapid detection of IgM heterophile antibodies in acute phase infections.

- Results in 5 minutes or less
- Plus/minus (+/-) readout
- IgM-specific
- No age restrictions
- >98% sensitivity; >99% specificity
- >99% agreement with slide hemagglutination and EIA
- Differentiates acute phase from past disease
- CLIA waived when using whole blood
- CLIA Moderately Complex when using serum or plasma



Catalog #	Qty	Description
20121	20 tests	QuickVue+ Mononucleosis Test Kit

QuickVue RSV 10 Test

Immunoassay for the qualitative detection of Respiratory Syncytial Virus from nasopharyngeal swab or nasopharyngeal aspirate/wash specimens.

- Results in 10 minutes or less
- 90% sensitivity with nasopharyngeal aspirate/wash
- 86% sensitivity with nasopharyngeal swab
- 3 steps nasopharyngeal swab, 1 step nasopharyngeal aspirate/wash
- 1 reagent
- CLIA Moderately Complex



Catalog #	Qty	Description
20222	25 tests	QuickVue RSV 10 Test Kit

QuickVue RSV Test

Immunoassay for the qualitative detection of Respiratory Syncytial Virus from nasopharyngeal swab, nasopharyngeal aspirate, or nasal/nasopharyngeal wash specimens.

- Results in 15 minutes or less
- 99% sensitivity with nasopharyngeal aspirate
- 92% sensitivity with nasopharyngeal swab
- 83% sensitivity with nasal/nasopharyngeal wash
- 3 steps nasopharyngeal swab, 1 step nasopharyngeal aspirate and nasal/nasopharyngeal wash with approximately 30 seconds hands-on time
- 1 reagent
- CLIA waived



Catalog #	Qty	Description
20193	20 tests	QuickVue RSV Test Kit

QuickVue Adenoviral conjunctivitis Test

Immunoassay for the visual, qualitative *in vitro* detection of Adenoviral antigens (hexon protein) directly from human eye fluid.

- Results in 10 minutes
- 90% sensitivity and 96% specificity
- Simple 4-step procedure
- Disposable test with no additional equipment needed to administer or interpret
- Reduce inappropriate antibiotic use
- CLIA waived



Catalog #	Qty	Description
20324	10 tests	QuickVue Adenoviral conjunctivitis Test Kit
RPS-ADSTD	1	QuickVue Adenoviral conjunctivitis External Controls

QuickVue+ Strep A Test

Immunoassay for the rapid qualitative detection of Group A Streptococcal antigen from throat swab specimens.

- Results in approximately 5 minutes
- Plus/minus (+/-) readout
- 98% overall agreement with SBA culture
- Two reagent procedure to reduce hands-on time
- Test Complete indicator lets you read the test at your convenience
- CLIA Moderately Complex



Catalog #	Qty	Description
20122	25 tests	QuickVue+ Strep A Test Kit
00354	1	Strep A Liquid Control Set
20227	50 swabs	Strep A Swabs

QuickVue In-Line Strep A Test

Unique In-Line immunoassay for the rapid qualitative detection of Group A Streptococcal antigen from throat swab specimens.

- Results in 5 minutes or less
- 96% overall agreement with SBA culture
- One easy step via In-Line extraction
- Single reagent method allows for less chance of operator error
- Individually packaged for convenient single-use testing and disposal
- First CLIA-waived Strep A test



Catalog #	Qty	Description
00343	25 tests	QuickVue In-Line Strep A Test Kit
00345	6 Pos/6 Neg	QuickVue In-Line Strep A Control Set
00347	75 swabs	Strep A Swab Pack

QuickVue Dipstick Strep A Test

Dipstick immunoassay for the rapid qualitative detection of Group A Streptococcal antigen from throat swab specimens.

- Results in 5 minutes or less
- 95% overall agreement with SBA culture
- High sensitivity at low levels of colony count
- CLIA waived



Catalog #	Qty	Description
20108	50 tests	QuickVue Dipstick Strep A Test Kit
00354	1	Strep A Liquid Control Set
20227	50 swabs	Strep A Swabs

QuickVue+ hCG Combo Test

Immunoassay for the qualitative detection of human chorionic gonadotropin (hCG) in serum or urine for the early detection of pregnancy.

- Results in 5 minutes (serum), 3 minutes (urine)
- Plus/minus (+/-) readout
- >99% accuracy
- 10 mIU/mL sensitivity, serum; 20 mIU/mL sensitivity, urine
- Detects low hCG levels as early as 2-3 days before expected menses
- CLIA waived when using urine
- CLIA Moderately Complex when using serum



Catalog #	Qty	Description
00178	30 tests	QuickVue+ hCG Combo Test Kit
00179	90 tests	QuickVue+ hCG Combo Test Kit
00272	1	hCG Control Set – Urine
00281	1	hCG Control Set – Serum

QuickVue hCG Combo Test

Immunoassay for the qualitative detection of human chorionic gonadotropin (hCG) in serum or urine for the early detection of pregnancy.

- Results in 5 minutes (serum), 3 minutes (urine)
- >99% accuracy
- 25 mIU/mL sensitivity in serum and urine
- Detects low hCG levels as early as 2-3 days before expected menses
- CLIA waived when using urine
- CLIA Moderately Complex when using serum



Catalog #	Qty	Description
20110	50 tests	QuickVue hCG Combo Test Kit
00272	1	hCG Control Set – Urine
00281	1	hCG Control Set – Serum

QuickVue hCG Urine Test

Immunoassay for the qualitative detection of human chorionic gonadotropin (hCG) in urine for the early detection of pregnancy.

- Results in 3 minutes or less
- >99% accuracy
- 25 mIU/mL sensitivity
- Detects low hCG levels as early as 2-3 days before expected menses
- CLIA waived



Catalog #	Qty	Description
20109	25 tests	QuickVue hCG Urine Test Kit
00272	1	hCG Control Set – Urine

QuickVue Chlamydia Test

Immunoassay for the qualitative detection of Chlamydia trachomatis antigen directly from endocervical swab or cytology brush specimens.

- Results in 12 minutes or less
- 92% sensitivity; 99% specificity (overall)
- Highly accurate in asymptomatic patient population: 94% sensitivity, 99% specificity
- Simple extraction procedure with just 2 reagents
- After extraction, just add the sample to the Test Cassette
- CLIA Moderately Complex



Catalog #	Qty	Description
0B006	25 tests	QuickVue Chlamydia Test Kit
20228	1	Chlamydia Swab Pack

QuickVue TLI H. pylori Stool Antigen Test

Rapid membrane enzyme immunoassay for the qualitative detection of *Helicobacter pylori* specific antigen in a single use cassette.

- Results in 30 minutes
- 97% sensitivity; 100% specificity
- Demonstrate loss of antigen following treatment
- Can be used with various sample types, including fresh, frozen, Cary Blair, or C&S samples
- CLIA Moderately Complex



Catalog #	Qty	Description
20343	25 tests	QuickVue TLI H. pylori Stool Antigen Test Kit

QuickVue TLI Campylobacter Test

Rapid membrane enzyme-linked immunosorbent assay for the qualitative detection of a Campylobacter-specific antigen in human fecal specimens.

- Results in 30 minutes
- >97% sensitivity; >99% specificity
- Does not rely on bacterial viability
- Can be performed with fresh, frozen, Cary Blair or C&S samples or specimens
- CLIA Moderately Complex



Catalog #	Qty	Description
20344	25 tests	QuickVue TLI Campylobacter Test Kit

QuickVue TLI Lactoferrin Test

Immunochromatographic test for the qualitative detection of elevated levels of lactoferrin, a marker for fecal leukocytes and an indicator of intestinal inflammation.

- Results in 10 minutes
- >100% sensitivity; >97% specificity
- Can be used with samples stored at room temperature for up to 2 weeks
- CLIA Moderately Complex



Catalog #	Qty	Description
20345	25 tests	QuickVue TLI Lactoferrin Test Kit

QuickVue H. pylori Test

Immunoassay for the rapid qualitative detection of IgG antibodies specific to *Helicobacter pylori*.

- Results in 5 minutes or less
- 92% overall agreement with EIA
- Simple, one-step procedure from only 2 hanging drops of whole blood, or 1 drop of serum or plasma
- CLIA waived when using whole blood specimens
- CLIA Moderately Complex when using serum or plasma



Catalog #	Qty	Description
0W009	10 tests	QuickVue H. pylori Test Kit
0W010	30 tests	QuickVue H. pylori Test Kit

QuickVue iFOB Test

(A Fecal Immunochemical or FIT test)

Immunochemical device intended for the qualitative detection of fecal occult blood.

- Results in 5-10 minutes
- Analytically more sensitive than Guaiac-based tests.*
- Analytical sensitivity: 50 ng hHb/mL buffer or 50 µg hHb/g feces
- Specific to human hemoglobin
- No dietary restrictions
- Only one specimen collection required
- CLIA waived



Catalog #	Qty	Description
20194	20 tests	QuickVue iFOB Test Kit
20196	10 sets	Patient Specimen Collection Kit
20201	50 tests	QuickVue iFOB Tray Pack (Test Cassettes)
20204	40 sets	Patient Specimen Collection Kit
20205	100 tests	Test Cassettes
20197	1	iFOB Control Set

* Park, Di et al. Am J Gastro (2010), 105: 2017-25



The QuickVue SARS Antigen Test has not been FDA cleared or approved but has been authorized by the FDA under an EUA for use by authorized laboratories for the detection of proteins from SARS-CoV-2, and influenza, not for any other viruses or pathogens. This assay is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of *in vitro* diagnostics for detection and/or diagnosis of COVID-19 under Section 564(b)(1) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 360bbb-3(b)(1), unless authorization is terminated or revoked sooner.