

## K201312 VITROS Immunodiagnostic Products NT-proBNP II Reagent Pack

Oct 4, 2021  
504 days to decisionK201312 · Product code: **NBC** · Chemistry  
Source: <https://www.510kdatabase.net/k201312/>

### SUBMISSION DETAILS

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Test, Natriuretic Peptide (NBC)
Date received	May 18, 2020
Decision date	Oct 4, 2021
Days to decision	504 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

### APPLICANT

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Company	<b>Ortho-Clinical Diagnostics</b>
Location	Rochester, NY, US
Contact	Leah Van De Water
510(k) history	38 submissions · 38 cleared · 1999-2024

Ortho-Clinical Diagnostics is an in vitro diagnostics company specializing in clinical laboratory testing and immunohematology. Now part of QuidelOrtho, the brand operates with global research and development centered in Rochester, New York. The company maintains a strong FDA 510(k) regulatory record with FDA 510(k) clearances from total submissions since 1999. Recent clearances span chemistry devices, immunology assays, and microbiology reagents, reflecting the company's focus on diagnostic platforms and assays for disease detection and blood compatibility testing. The V...

### CLINICAL EVIDENCE - NCT03548909

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#### VITROS Immunodiagnostic Products NT-proBNP II

Status	Completed - <i>No results published to ClinicalTrials.gov</i>
Enrollment	3246 patients (actual)
Study sites	25 sites
Condition studied	Heart Failure
Study type	Observational
Completion date	Oct 17, 2019
Sponsor	Ortho-Clinical Diagnostics, Inc. (Industry)

#### Primary outcome

Sensitivity and Specificity of the VITROS NT-proBNP II assay

#### Secondary outcome

Heart Failure Severity Assessment

Source: ClinicalTrials.gov / U.S. National Library of Medicine - [clinicaltrials.gov/study/NCT03548909](https://clinicaltrials.gov/study/NCT03548909)