VITROS Products
Immunodiagnostic

INSTRUCTIONS FOR USE B12

VITROS Immunodiagnostic Products Vitamin B12 Reagent Pack 1/2	REF	145 3489
VITROS Immunodiagnostic Products Vitamin B12/Folate Reagent Pack 3	REF	114 2561
VITROS Immunodiagnostic Products Vitamin B12 Calibrators	REF	154 0525

Rx ONLY

Intended Use

For *in vitro* diagnostic use only.

VITROS Immunodiagnostic Products Vitamin B12 Reagent Pack 1/2

For the quantitative measurement of vitamin B12 in human serum and plasma (EDTA or heparin) using the VITROS ECi/ECiQ/3600 Immunodiagnostic Systems and the VITROS 5600/XT 7600 Integrated Systems, to aid in the differential diagnosis of anemia.

VITROS Immunodiagnostic Products Vitamin B12/Folate Reagent Pack 3

For use in conjunction with the VITROS Vitamin B12 and VITROS Folate Reagent Packs 1 and 2 using the VITROS ECi/ECiQ/3600 Immunodiagnostic Systems and the VITROS 5600/XT 7600 Integrated Systems.

VITROS Immunodiagnostic Products Vitamin B12 Calibrators

For use in the calibration of the VITROS ECi/ECiQ/3600 Immunodiagnostic Systems and the VITROS 5600/XT 7600 Integrated Systems for the quantitative measurement of vitamin B12 in human serum and plasma (EDTA or heparin).

Summary and Explanation of the Test

Reduced concentrations of vitamin B12 may indicate the presence of vitamin dependent anemia. Elevated concentrations of vitamin B12 have been associated with pregnancy, the use of oral contraceptives and multivitamins and in myeloproliferative diseases, such as chronic granulocytic leukemia and myelomonocytic leukemia. An elevated concentration of vitamin B12 is not known to cause clinical problems. Measurement of vitamin B12 is intended to identify and monitor vitamin B12 deficiency. This can arise from the following; (1) defect in the secretion of Intrinsic Factor, resulting in inadequate absorption from food (pernicious anemia); [1] (2) gastrectomy and malabsorption due to surgical resection; and (3) a variety of bacterial or inflammatory diseases affecting the small intestine. [2 - 4]

Principles of the Procedure

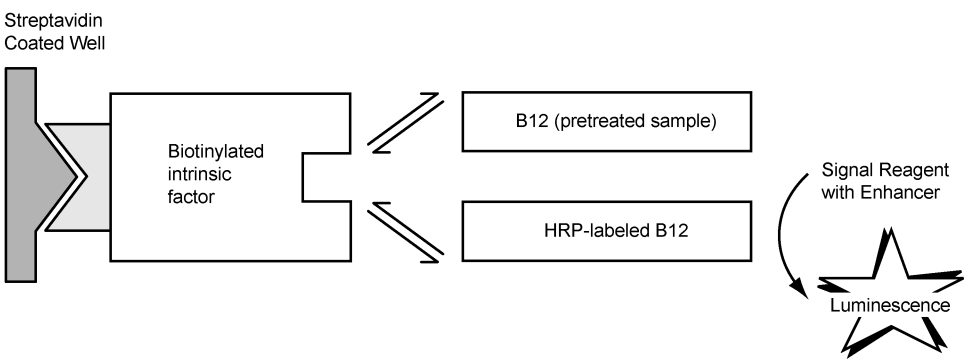
A competitive binding immunoassay technique is used, which depends on a competition between vitamin B12 present in the sample with a horseradish peroxidase (HRP)-labeled vitamin B12 conjugate for a limited number of binding sites on a biotinylated Intrinsic Factor present in the liquid phase. Vitamin B12 present in patient samples is released from its endogenous binding proteins by alkaline denaturation. Biotinylated Intrinsic Factor conjugate is added and incubated with the treated neutralized sample. An aliquot of the treated sample is transferred into a streptavidin coated well and B12-HRP conjugate added. Following a competitive binding reaction, the vitamin B12 Intrinsic Factor complexes are captured by streptavidin on the wells. Unbound materials are removed by washing.

The bound HRP conjugate is measured by a luminescent reaction. [5] A reagent containing luminogenic substrates (a luminol derivative and a peracid salt) and an electron transfer agent, is added to the wells. The HRP in the bound conjugate catalyzes the oxidation of the luminol derivative, producing light. The electron transfer agent (a substituted acetanilide) increases the level of light produced and prolongs its emission. The light signals are read by the system. The amount of HRP conjugate bound is indirectly proportional to the concentration of vitamin B12 present.

Test Type	System *	Incubation Time	Time to first result	Test Temperature	Reaction Sample Volume
Competitive binding assay	ECi/ECiQ, 3600, 5600, XT 7600	48 minutes (including denaturation)	57 minutes	37 °C	30 µL

* Not all products and systems are available in all countries.

Reaction Scheme



Warnings and Precautions

WARNING: Potentially Infectious Material

Human blood products provided as components of the VITROS Vitamin B12 Reagent Packs 1 and 2 and the VITROS Vitamin B12 Calibrators have been obtained from donors who were tested individually and who were found to be negative for hepatitis B surface antigen, and for antibodies to human immunodeficiency virus (HIV 1+2) and hepatitis C virus (HCV), using approved methods (enzyme immunoassays). Treat as if capable of transmitting infection.

Use caution when handling material of human origin. Consider all samples potentially infectious. No test method can offer complete assurance that hepatitis B virus, HCV, HIV 1+2 or other infectious agents are absent. Handle, use, store and dispose of solid and liquid waste from samples and test components, in accordance with procedures defined by appropriate national biohazard safety guideline or regulation (e.g. CLSI document M29). [6]

WARNING: Contains 2-Chloroacetamide (CAS 79-07-2) [7]

The VITROS Vitamin B12 Reagent Packs 1 and 2 and the VITROS Vitamin B12 Calibrators contain 0.5%, 0.2% and 2% 2-Chloroacetamide respectively. H361: Suspected of damaging fertility or the unborn child. H317: May cause an allergic skin reaction. P280: Wear protective gloves/protective clothing/eye protection/ face protection. P302 + P352: IF ON SKIN: Wash with plenty of soap and water. P333 + P313: If skin irritation or rash occurs: Get medical advice/attention. P363: Wash contaminated clothing before reuse. P308 + P313: IF exposed or concerned: Get medical advice/attention..

WARNING

WARNING

DANGER: Contains Sodium Hydroxide (CAS 1310-73-2) and Orthoboric acid (CAS 10043-35-3) [7]

The VITROS Vitamin B12/Folate Reagent Pack 3 contains 4.8% sodium hydroxide and 2.97% orthoboric acid. H314: Causes severe skin burns and eye damage. P280: Wear protective gloves/protective clothing/eye protection/face protection. P301 + P330 + P331: IF SWALLOWED: rinse mouth. Do NOT induce

vomiting. P303 + P361 + P353: IF ON SKIN (or hair): remove/take off immediately all contaminated clothing. Rinse skin with water/shower. P363: Wash contaminated clothing before reuse. P305 + P351 + P338: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. P310: Immediately call a POISON CENTER or doctor/physician.

Refer to www.Orthoclinicaldiagnostics.com for the Safety Data Sheets and for Ortho contact information.

DANGER

Reagents

Reagent Pack Contents

VITROS Vitamin B12 Reagent Pack 1/2

VITROS Vitamin B12 Reagent Pack 1 contains:

- 100 coated wells (streptavidin, bacterial; binds ≥3 ng biotin/well)
- 6.7 mL biotinylated Intrinsic Factor reagent (biotin-intrinsic factor, binds ≥1.05 ng B12/mL) in buffer with human serum albumin and antimicrobial agent
- 6.7 mL conjugate reagent (HRP-B12, ≥650 ng/mL) in buffer with human serum albumin and antimicrobial agent

VITROS Vitamin B12 Reagent Pack 2 contains:

- 100 uncoated wells
- 6.2 mL sample treatment (stabilization) reagent with antimicrobial agent

VITROS Vitamin B12/Folate Reagent Pack 3

VITROS Vitamin B12/Folate Reagent Pack 3 contains:

- 11.7 mL sample treatment (denaturation) reagent
- 15.6 mL sample treatment (neutralization) reagent
- Ancillary lot card (for use with Reagent Pack 3, colored yellow)

Reagent Pack Handling

- The VITROS Vitamin B12 Reagent Packs 1 and 2 and the VITROS Vitamin B12/Folate Reagent Pack 3 are supplied ready for use.
- These reagent packs contain homogeneous liquid reagents that do not require shaking or mixing prior to loading onto the system.
- Handle these reagent packs with care. Avoid the following:
  - allowing condensation to form on the packs
  - causing reagents to foam
  - agitation of the packs

Reagent Pack Storage and Preparation

	Reagent	Storage Condition		Stability
VITROS Vitamin B12 Reagent Packs 1 and 2	Unopened	Refrigerated	2–8 °C (36–46 °F)	expiration date
	Opened	On system	System turned on	≤12 weeks
	Opened	Refrigerated	2–8 °C (36–46 °F)	≤12 weeks
VITROS Vitamin B12/ Folate Reagent Pack 3	Unopened	Refrigerated	2–8 °C (36–46 °F)	expiration date
	Opened	3600/5600/XT 7600: On System	System turned on	≤8 weeks
	Opened	ECi/ECiQ: On system	System turned on	≤8 weeks
	Opened	3600/5600/XT 7600: Refrigerated	2–8 °C (36–46 °F)	≤8 weeks
	Opened	ECi/ECiQ: Refrigerated	2–8 °C (36–46 °F)	≤8 weeks

- The VITROS B12 Reagent Packs 1 and 2 and the VITROS Vitamin B12/Folate Reagent Pack 3 are suitable for use until the expiration date on the carton when stored and handled as specified. Do not use beyond the expiration date.
- Do not freeze unopened reagent packs.
- Load reagent packs directly from refrigerated storage to minimize condensation.
- Store opened refrigerated reagent packs in a sealed reagent pack storage box that contains dry desiccant.

Calibrator Contents

- 1 set of VITROS Vitamin B12 Calibrators 1 and 2 (vitamin B12 in buffer with human serum albumin and antimicrobial agent, 2.0 mL); nominal values 230 and 670 pg/mL (170 and 494 pmol/L)
- Lot calibration card (for use with Reagent Pack 1, colored green)
- Ancillary Lot card (for use with Reagent Pack 2, colored yellow)
- Protocol card (colored blue)
- 16 calibrator bar code labels (8 for each calibrator)

Calibrator Handling

- Use only with reagent packs (VITROS Vitamin B12 Reagent Pack 1) of the same lot number. VITROS Vitamin B12 Reagent Pack 2 is not linked by lot number to VITROS Vitamin B12 Reagent Pack 1 or VITROS Vitamin B12 Calibrators and may be used independently. Mix thoroughly by inversion and bring to 15–30 °C (59–86 °F) before use. Each pack contains sufficient for a minimum of 6 determinations of each calibrator.
- Handle calibrators in stoppered containers to avoid contamination and evaporation. To avoid evaporation, limit the amount of time calibrators are on the system. Refer to the operating instructions for your system. Return to 2–8 °C (36–46 °F) as soon as possible after use, or load only sufficient for a single determination.

Calibrator Storage and Preparation

Calibrator	Storage Condition		Stability
Unopened	Refrigerated	2–8 °C (36–46 °F)	expiration date
Opened	Refrigerated	2–8 °C (36–46 °F)	≤13 weeks
Opened	Frozen	≤-20 °C (≤-4 °F)	≤13 weeks

- The VITROS Vitamin B12 Calibrators are supplied ready for use.
- The VITROS Vitamin B12 Calibrators are suitable for use until the expiration date on the carton when stored and handled as specified. Do not use beyond the expiration date.
- Opened calibrators may be stored frozen (with no more than 1 freeze-thaw cycle).
- The VITROS Vitamin B12 test uses 30 µL of calibrator for each determination. The VITROS Vitamin B12 Calibrators may be used directly on the VITROS Immunodiagnostic and VITROS Integrated Systems. Alternatively, transfer an aliquot of each calibrator into a sample container (taking account of the minimum fill volume of the container), which may be bar coded with the labels provided. For details on minimum fill volume of sample cups or containers, refer to the operating instructions for your system.

Specimen Collection, Preparation and Storage

Patient Preparation

No special patient preparation is necessary.

Specimens Recommended

- Serum
- EDTA plasma
- Heparin plasma

Specimens Not Recommended

Do not use turbid specimens. Turbidity in specimens may affect test results.

Special Precautions

IMPORTANT:	Certain collection devices have been reported to affect other analytes and tests. [8] Owing to the variety of specimen collection devices available, Ortho Clinical Diagnostics is unable to provide a definitive statement on the performance of its products with these devices. Confirm that your collection devices are compatible with this test.

Specimen Collection and Preparation

- Collect specimens using standard procedures. [9 - 10]
- Thoroughly mix samples by inversion and bring to 15–30 °C (59–86 °F) before use.
- The VITROS Vitamin B12 test uses 30 µL of sample for each determination. This does not take account of the minimum fill volume of the chosen sample container. For details on minimum fill volume of sample cups or containers, refer to the operating instructions for your system.

Handling and Storage Conditions

- Handle samples in stoppered containers to avoid contamination and evaporation.
- The amount of time samples are on the system prior to analysis should be limited to avoid evaporation. Refer to the operating instructions for your system for further information.
- Return to 2–8 °C (36–46 °F) as soon as possible after use, or load sufficient volume for a single determination.
- Serum and plasma samples may be stored for up to 7 days at 2–8 °C (36–46 °F) or 4 weeks at -20 °C (-4 °F).
- Avoid repeated freeze-thaw cycles.

Testing Procedure

Materials Provided

- VITROS Immunodiagnostic Products Vitamin B12 Reagent Pack 1/2
- VITROS Immunodiagnostic Products Vitamin B12/Folate Reagent Pack 3
- VITROS Immunodiagnostic Products Vitamin B12 Calibrators

Materials Required but Not Provided

- VITROS Immunodiagnostic Products Signal Reagent
- VITROS Immunodiagnostic Products Universal Wash Reagent
- Quality control materials such as VITROS Immunodiagnostic Products Anemia Controls
- VITROS Immunodiagnostic Products Reagent Pack Storage Box (optional) with desiccant (for VITROS Vitamin B12 Reagent Packs 1 and 2)

Operating Instructions

Check the inventory regularly to aid the management of reagents and ensure that sufficient VITROS Signal Reagent, VITROS Universal Wash Reagent and calibrated reagent lots are available for the work planned. When performing panels of tests on a single sample, ensure that the sample volume is sufficient for the tests ordered.

For detailed information refer to the operating instructions for your system.

Note:	Do not use visibly damaged product.

Sample Dilution

Vitamin B12 concentrations above the measuring range should be reported as >1000 pg/mL (738 pmol/L). The dilution of samples in VITROS Vitamin B12 test is not supported.

Default Test Name

The default test name which will appear on patient reports is B12. The default short name that will appear on the test selection menus and laboratory reports is B12. These defaults may be reconfigured, if required. For detailed information refer to the operating instructions for your system.

Calibration

Calibration Procedure

- Calibration is lot specific; reagent packs and calibrators are linked by lot number. Reagent packs from the same lot may use the same calibration.
- A Master Calibration (a dose response curve covering the full calibration range) is established for each new reagent lot. Concentrations for the linked lot of calibrators are determined from the Master Calibration.
- Ensure that the Master Calibration for each new reagent lot is available on your system.
- Process calibrators in the same manner as samples. Calibration need not be programmed if bar code labels are used; load the calibrators in any order, calibration will be initiated automatically.
- When the calibrators are processed the signal expected for each calibrator is compared against the actual signal obtained. The Master Calibration is then rescaled to reflect the differences between the actual and expected signals. The validity of this calibration curve is assessed against a range of quality parameters, and if acceptable, it is stored for use with any reagent pack of that lot.
- The quality of calibration cannot be completely described by a single parameter. The calibration report should be used in conjunction with acceptable control values to determine the validity of the calibration.
- Recalibration is required after a pre-determined calibration interval, or when a different reagent lot is loaded.
- Calibration results are assessed against a range of quality parameters. Failure to meet any of the defined quality parameter ranges will be coded in the calibration report. For actions to be taken following a failed calibration refer to the operating instructions for your system.

Refer to the operating instructions for your system for detailed instructions on the calibration process.

When to Calibrate

- Calibrate when the VITROS Vitamin B12 Reagent Pack 1 and VITROS Vitamin B12 Calibrator lot changes.
- Calibration is not required for lot number changes to VITROS Vitamin B12 Reagent Pack 2 and VITROS Vitamin B12/ Folate Reagent Pack 3.
- Calibrate every 28 days.
- After specified service procedures have been performed.
- If quality control results are consistently outside of your acceptable range.

For additional information on when to calibrate, refer to the operating instructions for your system.

Traceability of Calibration

The calibration of the VITROS Vitamin B12 test is traceable to in-house reference calibrators which have been value assigned to correlate with another commercially available test.

Calibration Model

A modified four-parameter logistic curve fit function is used to construct the Master Calibration. The calibration process rescales the Master Calibration to establish a valid stored curve for the VITROS Immunodiagnostic and VITROS Integrated Systems.

Measuring Range (Reportable Range)

System	Measuring (Reportable) Range
3600 5600 XT 7600 ECi/ECiQ	159*–1000 pg/mL (117–738 pmol/L)

* lower limit of measuring range reported by the system software is based on the Limit of Detection.

The lower limit reported by the system can be reconfigured if desired. For details on how to reconfigure the lower limit refer to the operating instructions for your system.

Quality Control

Quality Control Material Selection

VITROS Anemia Controls are recommended for use with the VITROS Immunodiagnostic and VITROS Integrated Systems. The VITROS Anemia Controls contain 3 levels of vitamin B12 (low, medium and high). The performance of other commercial control fluids should be evaluated for compatibility with this test before they are used for quality control.

Control materials may show a difference when compared with other vitamin B12 methods if they contain high concentrations of preservatives, stabilizers, or other nonphysiological additives, or otherwise depart from a true human sample matrix.

Appropriate quality control value ranges must be established for all quality control materials used with the VITROS Vitamin B12 test.

Quality Control Procedure Recommendations

- Good laboratory practice requires that controls be processed to verify the performance of the test.
- Choose control levels that check the clinically relevant concentrations.
- To verify system performance, analyze control materials:
  - After calibration
  - According to local regulations or at least once each day that the test is being performed
  - After specified service procedures are performed

If quality control procedures within your laboratory require more frequent use of controls, follow those procedures.

- Analyze quality control materials in the same manner as patient specimens.
- If control results fall outside your acceptable range, investigate the cause before deciding whether to report patient results.
- Refer to published guidelines for general quality control recommendations. [11]

For more detailed information, refer to the operating instructions for your system.

Quality Control Material Preparation and Storage

Refer to the manufacturer's product literature for preparation, storage, and stability information.

Results

Results are automatically calculated by the VITROS Immunodiagnostic and VITROS Integrated Systems.

Reporting Units and Unit Conversion

Analyte results are quoted in units of pg/mL and pmol/L. To configure the units, refer to the operating instructions for your system.

Conventional	Alternate
pg/mL (pmol/L × 1.355)	pmol/L (pg/mL × 0.738)

Limitations of the Procedure

Known Interferences

The VITROS Vitamin B12 test was evaluated for interference consistent with CLSI document EP7. [12] Commonly encountered substances were tested on at least 2 lots of reagents.

Refer to "Specificity" for a list of other compounds tested that did not show interference.

Interferent	Interferent Concentration		Units = pg/mL		Units = pmol/L	
			Analyte Conc*	Bias**	Analyte Conc*	Bias**
Cobinamide dicyanide	9.60 µmol/L	1 mg/dL	219	147	162	108

* Average test concentration of replicate determinations using 3 different lots of reagent.

** Estimate of the average difference observed.

Note: These results are representative. The degree of interference at concentrations other than those listed might not be predictable from these results. Other interfering substances may be encountered in the patient population.

Other Limitations

- The results from this or any other diagnostic test should be used and interpreted only in the context of the overall clinical picture.
- Certain drugs and clinical conditions are known to alter B12 concentrations *in vivo*. For additional information, refer to one of the published summaries. [13 - 15]
- Biotin levels in serum remain elevated for up to 24 hours after oral or intravenous biotin administration. [16]

Expected Values and Interpretation of Results

It is recommended that each laboratory establish its own expected values for the population it serves.

Reference Interval

Units = pg/mL	Units = pmol/L
239–931	176–687

This reference interval is the central 95% of results of a study of 261 non-anemic patients between the ages of 18 and 65.

Interpretation of Results

For patient sample values outside your established reference interval, the system may be configured to display a flag 'LO' or 'HI'. For detailed information refer to the operating instructions for your system.

Performance Characteristics

Limit of Detection

The Limit of Detection (LoD) for VITROS Vitamin B12 is 159 pg/mL (117 pmol/L), determined consistent with NCCLS document EP17 [17] and with proportions of false positives (α) less than 5% and false negatives (β) less than 1%; based on 700 determinations, with 1 blank and 5 low-level samples. The Limit of Blank (LoB) is 92.9 pg/mL (68.6 pmol/L).

Limit of Blank and Limit of Detection

LoB*		LoD**	
pg/mL	pmol/L	pg/mL	pmol/L
92.9	68.6	159	117

* Limit of Blank, or the highest value likely to be observed with a sample containing no analyte, replaces the term "analytical sensitivity."

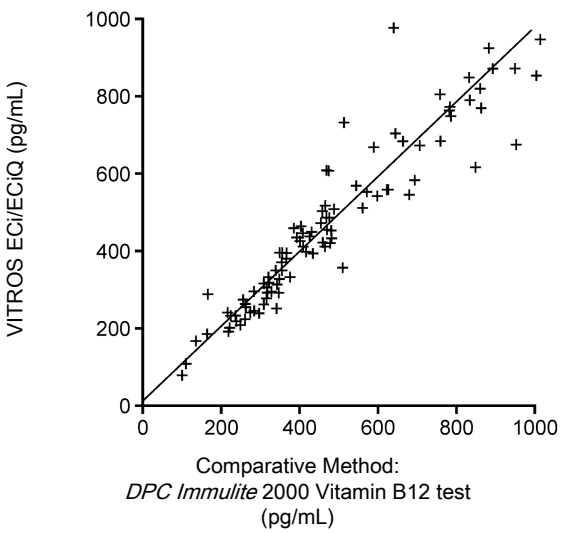
** Proportions of false positives (α) and false negatives (β) were less than 5% and 1% respectively; based on 700 determinations, with 1 blank and 700 low-level samples.

Accuracy (Method Comparison)

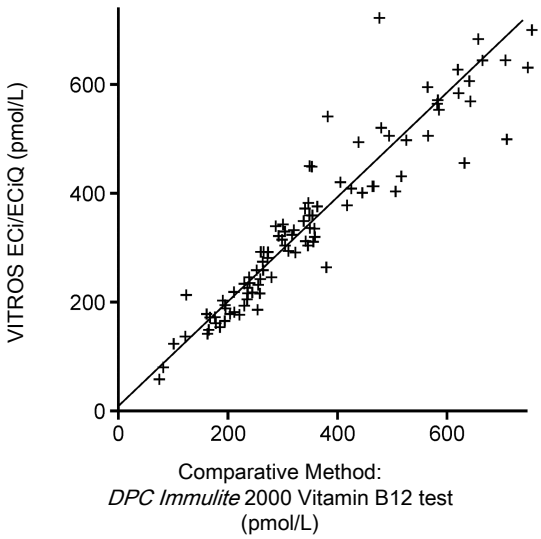
Accuracy was evaluated consistent with NCCLS document EP9 [18] The table shows the results of a method comparison study using patient samples analyzed on the VITROS ECi/ECiQ Immunodiagnostic System compared with those analyzed using the *DPC Immulite* 2000 Vitamin B12 test. The relationship between the 2 methods was determined by Deming regression. [19]

The table also shows the results of method comparison studies [20] using patient serum and plasma samples analyzed on the VITROS ECi/ECiQ Immunodiagnostic System compared with those analyzed using the VITROS 3600 Immunodiagnostic System and the VITROS 5600 Integrated System. The relationship between the 2 methods was determined by Passing and Bablok regression. [21]

Conventional Units



Alternate Units



System	n	Slope	Correlation Coefficient	Conventional Units (pg/mL) Range of Samples	Conventional Units (pg/mL) Intercept	Alternate Units (pmol/L) Range of Samples	Alternate Units (pmol/L) Intercept
ECi/ECiQ vs. Comparative Method	98	0.947	0.941	79.2–971	10.6	58.4–717	7.8
3600 vs. ECi/ECiQ	101	1.01	0.962	175–968	-14.7	129–714	-10.8
5600* vs. ECi/ECiQ	102	1.03	0.963	165–968	-12.6	122–714	-9.3

* Performance characteristics for the VITROS 5600 System are applicable to the VITROS XT 7600 System.

Precision

VITROS ECi/ECiQ Immunodiagnostic System

Precision was evaluated consistent with NCCLS document EP5. [22] Two replicates each of 3 control samples were tested on 2 separate occasions per day on at least 20 different days. The experiment was performed using 3 reagent lots on 3 different VITROS ECi/ECiQ Immunodiagnostic Systems. The data presented are a representation of the product performance.

VITROS 3600 Immunodiagnostic System and VITROS 5600 Integrated System

Precision was evaluated consistent with NCCLS document EP5. [23] Two replicates each of 3 control samples were tested on 2 separate occasions per day on at least 20 different days. The experiment was performed using 1 reagent lot on each system. The data presented are a representation of the product performance.

System	Units = pg/mL Mean B12 Conc.	Within-run* SD	Within-run* CV (%)	Within-calibration** SD	Within-calibration** CV (%)	Within-lab*** SD	Within-lab*** CV (%)	No. Observ.	No. Days
ECi/ECiQ system 1	214	3.79	1.8	10.2	4.8	12.1	5.7	88	22
	383	8.12	2.1	19.9	5.2	22.7	5.9	88	22
	706	10.8	1.5	32.6	4.6	38.6	5.5	88	22
ECi/ECiQ system 2	221	5.44	2.5	10.0	4.5	11.3	5.1	84	21
	385	6.51	1.7	23.6	6.1	25.8	6.7	84	21
	695	21.2	3.1	46.3	6.7	52.3	7.5	84	21
ECi/ECiQ system 3	218	2.46	1.1	6.97	3.2	7.61	3.5	88	22
	383	5.75	1.5	18.7	4.9	18.8	4.9	88	22
	719	14.9	2.1	29.2	4.1	31.5	4.4	88	22
3600	222	2.42	1.1	5.76	2.6	9.21	4.1	88	22
	357	4.16	1.2	16.5	4.6	17.7	4.9	88	22
	814	16.1	2.0	40.4	5.0	40.5	4.9	88	22
5600****	212	2.68	1.3	7.16	3.4	9.94	4.4	84	21
	341	3.59	1.1	16.7	4.9	20.4	5.7	84	21
	720	13.1	1.8	63.7	8.8	79.2	10.0	84	21

* Within-run (repeatability). Between Duplicate precision averaged over all runs

** Within-calibration. Total precision with weighted components of within-run, between–run and between-day variation

*** Within-lab. A measure of the effect of recalibration on total precision, calculated within reagent lot, using data from at least 4 calibrations

**** Performance characteristics for the VITROS 5600 System are applicable to the VITROS XT 7600 System.

System	Units = pmol/L							No. Observ.	No. Days
	Mean B12 Conc.	Within-run*		Within-calibration**		Within-lab***			
		SD	CV (%)	SD	CV (%)	SD	CV (%)		
ECi/ECiQ system 1	158	2.80	1.8	7.53	4.8	8.93	5.7	88	22
	283	5.99	2.1	14.7	5.2	16.8	5.9	88	22
	521	7.97	1.5	24.1	4.6	28.5	5.5	88	22
ECi/ECiQ system 2	163	4.01	2.5	7.38	4.5	8.34	5.1	84	21
	284	4.80	1.7	17.4	6.1	19.0	6.7	84	21
	513	15.6	3.1	34.2	6.7	38.6	7.5	84	21
ECi/ECiQ system 3	161	1.82	1.1	5.14	3.2	5.62	3.5	88	22
	283	4.24	1.5	13.8	4.9	13.9	4.9	88	22
	531	11.0	2.1	21.5	4.1	23.2	4.4	88	22
3600	164	1.79	1.1	4.25	2.6	6.80	4.1	88	22
	263	3.07	1.2	12.2	4.6	13.1	4.9	88	22
	601	11.9	2.0	29.8	5.0	29.9	4.9	88	22
5600****	156	1.98	1.3	5.28	3.4	7.34	4.4	84	21
	252	2.65	1.1	12.3	4.9	15.1	5.7	84	21
	531	9.67	1.8	47.0	8.8	58.4	10.0	84	21

* Within-run (repeatability). Between Duplicate precision averaged over all runs

** Within-calibration. Total precision with weighted components of within-run, between–run and between-day variation

*** Within-lab. A measure of the effect of recalibration on total precision, calculated within reagent lot, using data from at least 4 calibrations

**** Performance characteristics for the VITROS 5600 System are applicable to the VITROS XT 7600 System.

Specificity

Substances that do not Interfere

The VITROS Vitamin B12 test was evaluated for interference consistent with CLSI document EP7. [12] Of the compounds tested, none was found to cause a bias of >10% with the test at the concentrations indicated at vitamin B12 concentrations of
179–214 pg/mL (132–158 pmol/L).

Compound	Concentration	
Bilirubin	20 mg/dL	0.342 mmol/L
Biotin	2 µg/dL	0.082 µmol/L
Dipyrone	1000 mg/dL	30.0 mmol/L
Hemoglobin	150 mg/dL	0.091 mmol/L
Sodium Azide	50 mg/dL	7.69 mmol/L
Triolein	3000 mg/dL	33.9 mmol/L

References

1. Ardeman S, Chanarin I. Assay of gastric intrinsic factor in the diagnosis of Addisonian pernicious anaemia. British J. Haematology II, 305-314; 1965.
2. Chanarin I. (ed) The Megaloblastic Anaemias. ed. 3. Oxford: Blackwell Scientific Publications; 1990.
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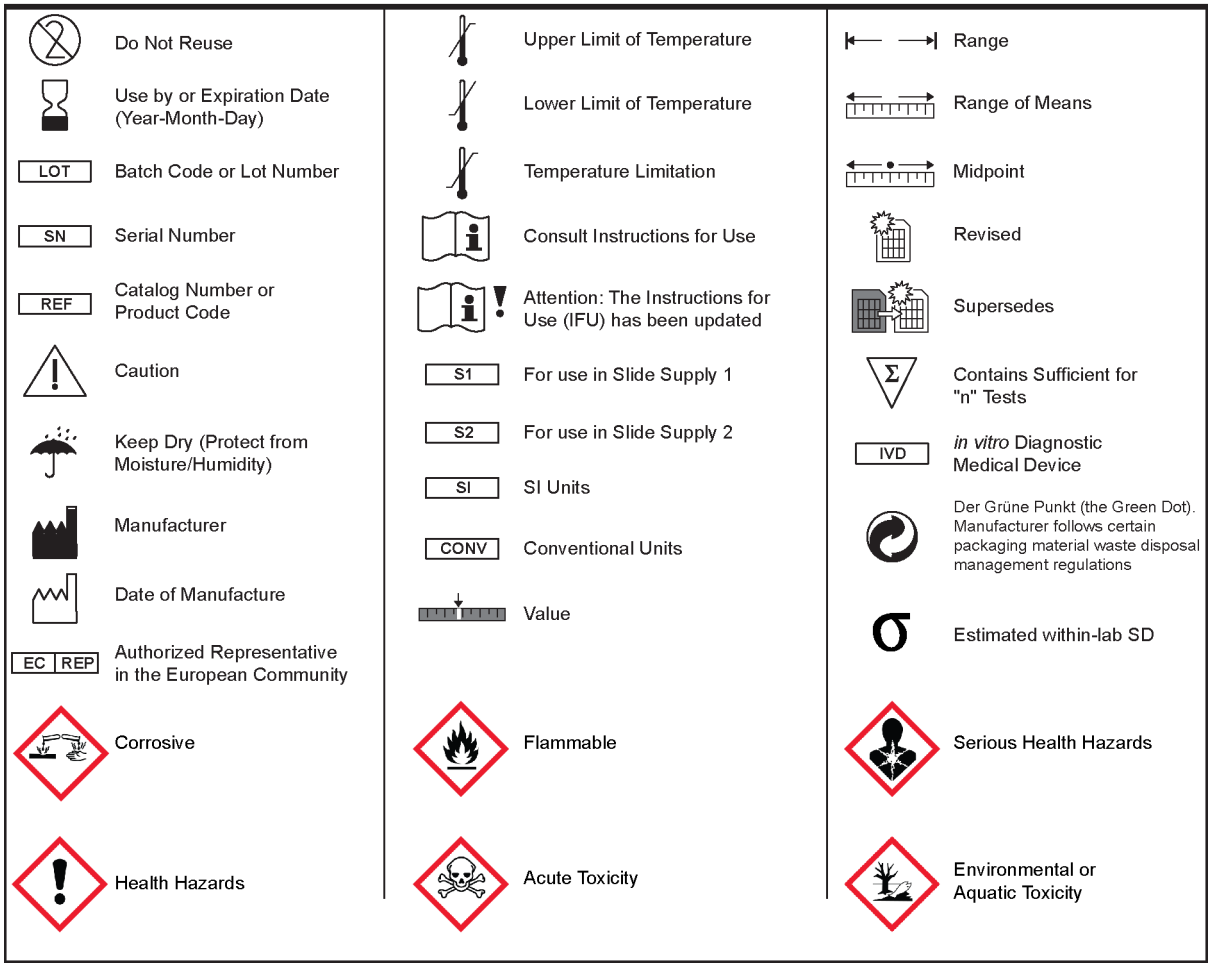
Glossary of Symbols

The following symbols may have been used in the labeling of this product.



Revision History

Date of Revision	Version	Description of Technical Changes*
2020-02-03	12.0	Reagent Pack Storage and Preparation: • Vitamin B12/Folate Reagent Pack 3 (3600/5600/XT 7600) – open stability changed from 4 weeks to 8 weeks
2019-09-06	11.1	• Glossary of Symbols: updated • Added EC Representative address
2017-10-04	11.0	• Added information for the VITROS XT 7600 Integrated System • Minor formatting and wording updates • References: updated • Glossary of Symbols: updated

* The change bars indicate the position of a technical amendment to the text with respect to the previous version of the document.

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