

**REF** ACC16-031 / ACC16-017

## Intended Use

This reagent is intended for the *in vitro* quantitative determination of Rheumatoid Factor (RF) in human serum using the Vital Diagnostics Turbi-Quick system.

## Summary<sup>1,2,3</sup>

Rheumatoid arthritis (RA) is a chronic, systemic inflammatory disease that affects approximately 1 % of the population. RA is characterised by an inflammation of synovial joints, which can lead to joint destruction and disability. Given this prognosis, the emphasis is very much on early diagnosis and treatment.

Autoantibody formation is a typical manifestation of RA and one such antibody routinely measured to assist in the clinical diagnosis and/or monitoring of treatment is Rheumatoid Factor (RF). The presence of serum RF is one of seven criteria recommended by the American College of Rheumatology (ACR) for the diagnosis of RA.

RF consists of autoantibodies, mostly of the Ig-M class, that are directed against the Fc fragment of IgG. High concentrations of RF may be associated with more destructive disease and a worse prognosis.

The specificity of RF for RA though is not optimal, given the fact that RF may also be present in a number of other autoimmune disorders (e.g. SLE, sarcoidosis and Sjorgens syndrome), infectious disorders and in healthy elderly populations.

## Methodology<sup>4</sup>

The classical RF was initially detected as an IgM antibody that agglutinated sheep erythrocytes coated with rabbit IgG. Later latex particles with human IgG were used and these methods have been subsequently automated using turbidimetry.

The Turbi-Quick RF is a turbidimetric procedure in which RF present in the sample combines with human IgG sensitised latex in the reagent, to produce an insoluble antigen–antibody complex. The increase in turbidity is measured by the Turbi-Quick as an increase in absorbance, which is directly proportional to the concentration of RF in the sample.

Results are automatically calculated and expressed in IU/mL of RF (World Health Organisation International Standard)

## Reagents

### Composition

Active Ingredients	Concentration
<b>BUFFER</b>	
Glycine	40mmol/L
Detergent	0.1%
NaCl	9g/L
<b>LATEX</b>	
Glycine buffer	200mmol/L
Human IgG sensitised latex	variable

## Warnings And Precautions

For *in vitro* diagnostic use.

Reagents contain Sodium azide which may react with copper or lead plumbing, forming copper or lead azide which may explode on percussion. Flush drains with water thoroughly after disposing of fluids containing sodium azide.

Components of human origin have been tested with approved methods and found to be negative for the presence of HIV 1 and HIV 2 antibodies as well as for Hep B surface antigen and anti-hepatitis C antibodies. However, reagent should be handled as if potentially infectious.

## Preparation

Reagents are ready for use as packaged.

## Storage And Stability

Store the reagent at 2 to 8°C. Capped reagents are stable to the expiration date on the bottle label. Do not freeze reagents. Do not use reagents beyond the stated expiration date

## Specimens

### Serum And Plasma Collection And Storage<sup>5</sup>

Use fresh serum. If the test cannot be carried out on the same day the serum may be stored at 2 to 8°C for 48 hours. If stored for a longer period, the sample should be frozen. Thawed samples should be mixed well prior to use. Avoid repeated freezing and thawing.

## Procedure

### Materials Provided

The Rheumatoid Factor kit includes the following components:

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<b>BUFFER</b>	2 x 11.25 mL	4 x 11.25 mL
<b>LATEX</b>	1 x 2.5 mL	2 x 2.5 mL

### Materials Required But Not Provided

Pipette 100 – 1000 µL

Pipette 10 – 100 µL

Cuvettes and micro stirrers (Reference code ACC16-037)

Normal Saline solution (9 g/L)

### Assay Procedure<sup>6</sup>

1. Insert the RF Turbi-Quick smart card (included with the RF Turbi-Kit) and select filter position A (578nm) in accordance with the directions in the User Manual.
2. Pre-dilute samples and controls, using normal saline (9g/L) 1:10. e.g. 50 µL of sample or control + 450 µL of NaCl (9 g/L).
3. Prepare an appropriate number of Turbi-Quick cuvettes by pre-mixing 450 µL **BUFFER** and 50 µL **LATEX**
4. Incubate 4 cuvettes (or if less than 4, the total number of cuvettes) in the pre-incubation positions on the Turbi-Quick for at least 1 minute.
5. Transfer the cuvette in Position 1 to the reading channel and when prompted by the instrument display, add 80 µL of sample or control.
6. Record result displayed after the programmed reaction time (300 seconds).
7. Repeat steps 5 & 6 using tubes in pre-incubation positions 2, 3 and 4, making sure to follow the prompts on the display.

Record all results. Refer to the user manual for additional information.

### Calibration

Calibration is not required. Lot specific calibration data is stored on the Lot specific Turbi-Kit smart card included with each Turbi-Kit. For further details, please refer to the User Manual.

## Quality Control

Vital Diagnostics recommends that normal and abnormal Turbi-Quick control material (Ref. ACC16-027) be included as unknown samples an run at least once per day or in accordance with laboratory procedures, when a new bottle of reagent is used, preventative maintenance is carried out on the analyser or a critical component is replaced and with every new lot number of reagent.

Control recoveries falling outside the acceptable limits of performance (assigned range) indicates the assay may be out of control and should be investigated. If one or all controls fall outside the acceptable limits of performance, repeat the assay with the same controls. If control values recovered on the repeat run are not acceptable repeat with new/fresh control samples. If the above actions do not rectify the problem, call Vital Diagnostics Technical Support or authorised Vital Diagnostics Distributor.

## Limitations

### Interfering Substances

For additional information, refer to Effects of Drugs on Clinical Laboratory Tests<sup>7</sup> and Effects of Pre-Analytical Variables on Clinical Laboratory Tests<sup>8</sup>.

The results of this assay should only be interpreted in conjunction with other diagnostic test results, clinical findings and the patient's medical history.

### Indications of reagent deterioration

Turbidity. Failure to recover control values within the assigned range.

## Limits And Ranges

### Measuring Range

0 – 250 IU/mL

### Detection Limit

2.5 IU/mL

### Hook Effect

> 2000 IU/mL



### Expected Values

0 – 20 IU/mL

The quoted range should serve as a guide only. Vital Diagnostics recommends that each laboratory verify this range or establishes a reference interval for the population that it services<sup>9</sup>.














## References

1. Coenen D, Verschueren P, Westhovens R, et al. Technical and diagnostic performance of 6 assays for the measurement of citrullinated protein / peptide antibodies in the diagnosis of rheumatoid arthritis. Clin Chem 2007;53:498-504.
2. Sinclair D, Hull RG. Why do general practitioners request rheumatoid factor? A study of symptoms, requesting patterns and patient outcome. Ann Clin Biochem 2003;40:131-7.
3. Kapitany A, Szabo Z, Lakos G, et al. Associations between anti-ccp antibody and rheumatoid factor levels and hla-dr4 expression in Hungarian patients with rheumatoid arthritis. IMAJ 2008;10:32-6.
4. Jaskowski TD, Hill HR, Russo K, et al. Relationship between rheumatoid factor isotypes and IgG anti-cyclic citrullinated peptide antibodies. The Journal of Rheumatology 2010;37:1582-8.
5. Procedures for the Handling and Processing of Blood Specimens; Approved Guideline - 3rd Ed. CSLI (formerly NCCLS) Document H18-A3 (ISBN 1-56238-555-0), 2004.
6. Turbi-Quick User Manual.
7. Young DS. Effects of drugs on clinical laboratory tests. 5th Ed. Washington DC: AACC press; 2000. 2200 pp.
8. Young DS. Effects of preanalytical variables on clinical laboratory tests. 3rd Ed. Washington DC: AACC press; 2007. 1917 pp
9. Wachtel. M. Et. al. Creation and Verification of Reference Intervals. Laboratory Medicine 1995; 26:593-7.

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## GLOSSARY OF SYMBOLS

	Manufacturer		Batch code / Lot number		In vitro diagnostic medical device
	Contents		Caution		Consult instructions for use
	Catalog number		Temperature limitation		Use by / Expiration date
	Buffer		Latex		Authorized Representative in the European Community
	Biological risks				