PROMETHEUS®
Therapeutics & Diagnostics
For the person in every patient

PROMETHEUS® TPMT Enzyme
Cat. # 3320

Test Description

PROMETHEUS® TPMT Enzyme testing provides a quantitative analysis of a patient's thiopurine methyltransferase (TPMT) enzyme activity level. Because each patient metabolizes thiopurines differently, the efficacy and toxicity of thiopurines can vary widely from patient to patient. Knowledge of the TPMT enzyme phenotype may reduce time of response, allow physicians to individualize dosing, identify patients in whom thiopurine therapy should be avoided and help reduce the risk of leukopenia.

- A quantitative analysis (phenotype) of TPMT Enzyme activity levels
- **Specimen Requirements** - 5.0 ml Whole Blood in EDTA / Lavender Top Tube
- **Shipping Requirements** – Ambient or cold pack (Do Not Freeze)
- **Storage /Stability** – 24 hours ambient, 8 days refrigerated
- **Turn Around Time** – 3 business days from date of receipt

Test Information

Catalog Number	Test Name	Assay	Reference Value	Result Identifier*
3320	TPMT Enzyme	Phenotype	Normal TPMT Activity: >21.0 EU/mL; Intermediate TPMT Activity: 6.0 – 21.0 EU/mL; Low TPMT Activity: <6.0 EU/mL	A00066

*Result identifier provided for use in HL7 applications.

Laboratory Description

- Prometheus is located in San Diego, CA. **Tax ID#** 33-0685754 **NPI#** 1073642641.
- Licensed in several states including New York and California.
- This test was developed and its performance characteristics determined by Prometheus Laboratories Inc. It has not been cleared or approved by the U.S. Food and Drug Administration. Prometheus Laboratories Inc. is a CAP-accredited CLIA laboratory.

CPT Codes (as applied by Prometheus)

- **82657,** TPMT (thiopurine S-methyltransferase) enzyme activity in peripheral RBC
- **82542,** Quantitative HPLC (High Pressure Liquid Chromatography) for 6-methyl-thioguanine

Literature References

- Seidman EG, Clinical use and practical application of TPMT enzyme and 6-mercaptopurine metabolite monitoring in IBD. *Gastroterol Disord.* 2003;3(suppl 1):S30-S38.
- Stolk JN, Boerbooms AM, de Abreu RA, et al. Reduced thiopurine methyltransferase activity and development of side effects of azathioprine treatment in patients with rheumatoid arthritis. *Arthritis Rheum.* 1998;41(10):1858-1866.

PTM16005 01/16

Thiopurine Methyltransferase, RBC

0092066

Ordering Recommendation

Screening test to detect risk for severe bone marow toxicity (myelosuppression) when exposed to standard dosing of thiopurine drugs.

Additional Technical Information

ARUP Consult® Disease Topics

- Thiopurine Methyltransferase Testing - TPMT
- Rheumatoid Arthritis - RA
- Inflammatory Bowel Disease - IBD
- Organ Transplantation - Immunosuppressive Drugs

View All...

Mnemonic

TPMT RBC

Methodology

Enzymatic/Quantitative Liquid Chromatography-Tandem Mass Spectrometry

Performed

Mon, Wed, Fri

Reported

3-4 days

New York DOH Approval Status

This test is New York DOH approved.

Submit With Order

Specimen Required

Patient Preparation:

Collect: Lavender (EDTA), pink (K_2EDTA), or green (sodium or lithium heparin).

Specimen Preparation: Transport 5 mL whole blood. (Min: 3 mL)

Storage/Transport Temperature: Refrigerated.

Unacceptable Conditions: Gel separator tubes. Specimens collected in sodium fluoride/potassium oxalate (gray). Hemolyzed, frozen, or room temperature specimens.

Remarks:

Stability: Ambient: 3 hours; Refrigerated: 6 days; Frozen: Unacceptable

Reference Interval

Normal TPMT activity: 24.0-44.0 U/mL - Individuals are predicted to be at low risk of bone marrow toxicity (myelosuppression) as a consequence of standard thiopurine therapy; no dose adjustment is recommended.

Intermediate TPMT activity: 17.0-23.9 U/mL - Individuals are predicted to be at intermediate risk of bone marrow toxicity (myelosuppression), as a consequence of standard thiopurine therapy; a dose reduction and therapeutic drug management is recommended.

Low TPMT activity: < 17.0 U/mL - Individuals are predicted to be at high risk of bone marrow toxicity (myelosuppression) as a consequence of standard thiopurine dosing. It is recommended to avoid the use of thiopurine drugs.

High TPMT activity: > 44.0 U/mL - Individuals are not predicted to be at risk for bone marrow toxicity (myelosuppression) as a consequence of standard thiopurine dosing, but may be at risk for therapeutic failure due to excessive inactivation of thiopurine drugs. Individuals may require higher than the normal standard dose. Therapeutic drug management is recommended.

Interpretive Data

The TPMT, RBC assay is used as a screen to detect individuals with low and intermediate TPMT activity who may be at risk for myelosuppression when exposed to standard doses of thiopurines, including azathioprine (Imuran) and 6-mercaptopurine (Purinethol). TPMT is the primary metabolic route for inactivation of thiopurine drugs in the bone marrow. When TPMT activity is low, it is predicted that proportionately more 6-mercaptopurine can be converted into the cytotoxic 6-thioguanine nucleotides that accumulate in the bone marrow causing excessive toxicity. The activity of TPMT is measured by the nanomoles of 6-methylmercaptopurine (inactive metabolite) produced per 1 mL of packed red blood cells, (U/mL).

TPMT phenotype testing does not replace the need for clinical monitoring of patients treated with thiopurine drugs. Genotype for TPMT cannot be inferred from TPMT activity (phenotype). Phenotype testing should not be requested for patients currently treated with thiopurine drugs. Current TPMT phenotype may not reflect future TPMT phenotype, particularly in patients who received blood transfusion within 30-60 days of testing. TPMT enzyme activity can be inhibited by several drugs such as: naproxen (Aleve), ibuprofen (Advil, Motrin), ketoprofen (Orudis), furosemide (Lasix), sulfasalazine (Azulfidine), mesalamine (Asacol), olsalazine (Dipentum), mefenamic acid (Ponstel), thiazide diuretics, and benzoic acid inhibitors. TPMT inhibitors may contribute to falsely low results; patients should abstain from these drugs for at least 48 hours prior to TPMT testing. Falsely low results may also occur as a result of inappropriate specimen handling and hemolysis.

Statement B: This test was developed and its performance characteristics determined by ARUP Laboratories. The U.S. Food and Drug Administration has not approved or cleared this test; however, FDA clearance or approval is not currently required for clinical use. The results are not intended to be used as the sole means for clinical diagnosis or patient management decisions.

Note

This assay measures only enzyme activity.

CPT Code(s)

82657

Components

Component Test Code*	Component Chart Name	LOINC
0092067	Thiopurine Methyltransferase	53819-9

** Component test codes cannot be used to order tests. The information provided here is not sufficient for interface builds; for a complete test mix, please view this test within the Laboratory Test Directory found at www.aruplab.com*

Aliases

- TPMT
- TPMT Enzyme
- TPMT Erythrocytes
- TPMT-RBC