

## Overview

### Useful For

Monitoring metallic prosthetic implant wear and local tissue destruction in failed hip arthroplasty constructs

This test is **not useful for** assessment of nutritional status or potential cobalt toxicity.

### Special Instructions

- [Trace Metals Analysis Specimen Collection and Transport](#)

### Method Name

Inductively Coupled Plasma-Mass Spectrometry (ICP-MS)

### NY State Available

Yes

## Specimen

### Specimen Type

Synovial Fluid

### Ordering Guidance

This test should only be used in individuals with metallic prosthetic implants. The significance of cobalt concentrations in synovial fluid in patients without implants is unknown.

### Specimen Required

**Patient Preparation:** High concentrations of gadolinium and iodine are known to interfere with most metal tests. If either gadolinium- or iodine-containing contrast media has been administered, a specimen should not be collected for at least 96 hours

**Container/Tube:** Royal blue top (metal-free EDTA)

**Specimen Volume:** 1 mL

**Collection Instructions:** See [Trace Metals Analysis Specimen Collection and Transport](#) for complete instructions.

**Additional Information:** Cobalt is present in the black rubber plunger seals found in most disposable syringes. As a result, synovial fluid should not be collected in these devices as contamination may occur.

### Specimen Minimum Volume

0.4 mL

### Reject Due To

Gross hemolysis	OK
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Gross lipemia	OK
Gross icterus	OK

### Specimen Stability Information

Specimen Type	Temperature	Time	Special Container
Synovial Fluid	Refrigerated (preferred)	90 days	
	Ambient	90 days	
	Frozen	90 days	

### Clinical & Interpretive

#### Clinical Information

Per FDA recommendations, orthopedic surgeons should consider measuring and following serial cobalt (Co) concentrations in EDTA anticoagulated whole blood in symptomatic patients with metal-on-metal hip implants as part of their overall clinical evaluation. However, a recent publication(1) has shown synovial fluid measurements were superior to whole blood and serum Co concentrations in predicting local tissue destruction in failed hip arthroplasty constructs.

Prosthetic devices produced by Depuy Company, Dow Corning, Howmedica, LCS, PCA, Osteonics, Richards Company, Tricon, and Whiteside are typically made of chromium, Co, and molybdenum. This list of products is incomplete, and these products' compositions change occasionally; see each prostheses' product information for composition details.

Co is a naturally occurring, hard, grey element widely distributed in the environment. It is used to produce alloys in the manufacturing of aircraft engines, cutting tools, and some artificial hip and knee joint prosthesis devices.

Co is an essential cofactor for vitamin B12, which is necessary for neurological function, brain function, and the formation of blood. For most people, food is the largest source of Co intake. The greatest environmental exposure occurs in mining processes, cemented tungsten-carbide industry, Co powder industry, and alloy production industry.

Co is not highly toxic; however large doses may produce adverse clinical manifestations. Acute symptoms include pulmonary edema, allergy, nausea, vomiting, hemorrhage, and renal failure. Chronic exposure to Co-containing hard metal (dust or fume) can result in a serious lung disease called "hard metal lung disease," which is a type of pneumoconiosis (lung fibrosis). Furthermore, inhalation of Co particles can cause respiratory sensitization, asthma, shortness of breath, and decreased pulmonary function. Even though the primary route of occupational exposure to Co is the respiratory tract, skin contact is also important because dermal exposures to hard metal and cobalt salts can result in significant systemic uptake. Sustained exposures can cause skin sensitization, which may result in eruptions of contact dermatitis. In cases of suspected toxicity, blood, serum, or urine concentrations of Co can be checked. Vitamin B12 should be used to assess nutritional status.

#### Reference Values

0-17 years: Not established

> or =18 years: <19.8 ng/mL

#### Interpretation

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Based on an internal study, synovial fluid cobalt concentrations of 19.8 ng/mL or above were more likely due to a metal reaction (eg, adverse local tissue reaction [ALTR]/adverse reaction to metal debris [ARMD]) versus a nonmetal reaction in patients undergoing metal-on-metal revision (sensitivity of 92.3% and specificity of 96.3%).

**Cautions**

This test is intended for monitoring of implant wear and should not be ordered to assess nutritional status or potential cobalt toxicity.

Because this test uses mass spectrometry detection, the radioactive form of cobalt, (<sup>60</sup>Co), is not quantified.

Specimen collection procedures for cobalt require special specimen collection tubes, rigorous attention to ultraclean specimen collection and handling procedures, and analysis in an ultraclean facility. Elevated trace element concentrations in the absence of corroborating clinical information do not independently predict prosthesis wear or failure.

**Clinical Reference**

1. Houdek MT, Taunton MJ, Wyles CC, Jannetto PJ, Lewallen DG, Berry DJ: Synovial fluid metal ion levels are superior to blood metal ion levels in predicting an adverse local tissue reaction in failed total hip arthroplasty. *J Arthroplasty*. 2021 Sep;36(9):3312-3317.e1. doi: 10.1016/j.arth.2021.04.034
2. Eltit F, Assiri A, Garbuz D, et al: Adverse reactions to metal on polyethylene implants: Highly destructive lesions related to elevated concentration of cobalt and chromium in synovial fluid. *J Biomed Mater Res A*. 2017 Jul;105(7):1876-1886. doi: 10.1002/jbm.a.36057
3. Lass R, Grubl A, Kolb A, et al: Comparison of synovial fluid, urine, and serum ion levels in metal-on-metal total hip arthroplasty at minimum follow-up of 18 years. *J Orthop Res*. 2014 Sept;32(9):1234-1240. doi: 10.1002/jor.22652
4. De Pasquale D, Stea S, Squarzoni S, et al: Metal-on-metal hip prostheses: Correlation between debris in the synovial fluid and levels of cobalt and chromium ions in the bloodstream. *Int Orthop*. 2014 Mar;38(3):469-475. doi: 10.1007/s00264-013-2137-5

**Performance****Method Description**

Cobalt is analyzed by inductively coupled plasma-mass spectrometry (ICP-MS).(Unpublished Mayo method)

**PDF Report**

No

**Day(s) Performed**

Wednesday

**Report Available**

2 to 8 days

**Specimen Retention Time**

14 days

**Performing Laboratory Location**

Rochester

**Fees & Codes****Fees**

- Authorized users can sign in to [Test Prices](#) for detailed fee information.
- Clients without access to Test Prices can contact [Customer Service](#) 24 hours a day, seven days a week.
- Prospective clients should contact their Regional Manager. For assistance, contact [Customer Service](#).

**Test Classification**

This test was developed, and its performance characteristics determined by Mayo Clinic in a manner consistent with CLIA requirements. This test has not been cleared or approved by the US Food and Drug Administration.

**CPT Code Information**

83018

**LOINC® Information**

Test ID	Test Order Name	Order LOINC® Value
COSY	Cobalt, Synovial Fl	23842-8

Result ID	Test Result Name	Result LOINC® Value
606352	Cobalt, Synovial Fl	23842-8