

## Overview

### Useful For

Diagnosis of acromegaly and assessment of treatment efficacy when interpreted in conjunction with results from glucose suppression test

Diagnosis of human growth hormone deficiency when interpreted in conjunction with results from growth hormone stimulation test

This test is **not** intended for use as a screen for acromegaly.

This test has **limited value** in assessing growth hormone secretion in normal children.

### Method Name

Immunoenzymatic Assay

### NY State Available

No

## Specimen

### Specimen Type

Serum

### Ordering Guidance

For assessing growth hormone secretion in normal children, the recommended test is IGFMS / Insulin-Like Growth Factor 1, Mass Spectrometry, Serum.

For acromegaly screening, the preferred test is IGFGP / Insulin-Like Growth Factor 1 and Insulin-Like Growth Factor-Binding Protein 3 Growth Panel, Serum.

### Specimen Required

#### Patient Preparation:

**Fasting: 8 hours, required**

**Supplies:** Sarstedt Aliquot Tube, 5 mL (T914)

#### Container/Tube:

**Preferred:** Serum gel

**Acceptable:** Red top

**Specimen Volume:** 0.6 mL

#### Collection Instructions:

1. Centrifuge and aliquot serum into a plastic vial.

2. If multiple specimens are collected, submit each vial under a separate order.
3. Label specimens appropriately with the corresponding collection times.

## Forms

If not ordering electronically, complete, print, and send an [Oncology Test Request](#) (T729) with the specimen.

## Specimen Minimum Volume

0.5 mL

## Reject Due To

Gross hemolysis	Reject
Gross lipemia	OK
Gross icterus	OK

## Specimen Stability Information

Specimen Type	Temperature	Time	Special Container
Serum	Refrigerated (preferred)	7 days	
	Frozen	90 days	

## Clinical & Interpretive

### Clinical Information

The anterior pituitary secretes human growth hormone (hGH) in response to exercise, deep sleep, hypoglycemia, and protein ingestion. hGH stimulates hepatic insulin-like growth factor-1 and mobilizes fatty acids from fat deposits to the liver. Hyposecretion of hGH causes dwarfism in children. Hypersecretion causes gigantism in children or acromegaly in adults.

Because hGH levels in normal and diseased populations overlap, hGH suppression and stimulation tests are needed to evaluate conditions of hGH excess and deficiency; random hGH levels are inadequate.

### Reference Values

Males:

- 2-<7 years:\* 0.05-5.11 ng/mL
- 7-<12 years:\* 0.02-4.76 ng/mL
- 12-<14 years:\* 0.02-6.20 ng/mL
- 14-<18 years:\* 0.02-3.81 ng/mL
- > or =18 years: 0.02-0.97 ng/mL

Females:

- 2-<7 years:\* 0.05-5.11 ng/mL
- 7-<12 years:\* 0.02-4.76 ng/mL

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12-<14 years:\* 0.02-6.20 ng/mL

14-<18 years:\* 0.03-5.22 ng/mL

> or =18 years: 0.02-3.61 ng/mL

\*Source: Karbasy K, Lin DC, Stoianov A, et al. Pediatric reference value distributions and covariate-stratified reference intervals for 29 endocrine and special chemistry biomarkers on the Beckman Coulter Immunoassay Systems: a CALIPER study of healthy community children. *Clin Chem Lab Med.* 2016;54(4):643-657. doi:10.1515/cclm-2015-0558

Reference intervals for patients younger than 2 years have not been established.

For International System of Units (SI) conversion for Reference Values, see

[www.mayocliniclabs.com/order-tests/si-unit-conversion.html](http://www.mayocliniclabs.com/order-tests/si-unit-conversion.html)

### Interpretation

**Acromegaly:** For suppression testing, normal subjects have a nadir human growth hormone (hGH) concentration below 0.3 ng/mL after ingestion of a 75-gram glucose dose. Patients with acromegaly fail to show normal suppression. Using the Access ultrasensitive hGH assay, a cutoff of 0.53 ng/mL for nadir hGH was found to differentiate patients most accurately with acromegaly in remission from active disease with a sensitivity of 97% (95% CI, 83%-100%) and a specificity of 100% (95% CI, 82%-100%).(1)

**Deficiency:** A normal response following stimulation tests is a peak hGH concentration above 5 ng/mL in children and above 4 ng/mL in adults. For children, some experts consider hGH values between 5 ng/mL and 8 ng/mL equivocal and only GH peak values greater than 8 ng/mL as truly normal. Low levels, particularly under stimulation, indicate hGH deficiency.

### Cautions

As the human growth hormone (hGH) test has limited value in assessing growth hormone secretion in normal children, IGFMS / Insulin-Like Growth Factor 1, Mass Spectrometry, Serum is recommended as the first test for assessing deficient or excess growth during childhood and adolescent development. IGF1 reference intervals for Tanner stages are available. Suspected causes of dwarfism should be diagnosed with the aid of provocative testing.

Elevated levels of hGH indicate the possibility of gigantism or acromegaly but must be confirmed with stimulation and suppression testing.

Growth hormone is secreted in surges; single measurements are of limited diagnostic value.

In rare cases, some individuals can develop antibodies to mouse or other animal antibodies (often referred to as human anti-mouse antibodies [HAMA] or heterophile antibodies), which may cause interference in some immunoassays. Caution should be used in interpretation of results and the laboratory should be alerted if the result does not correlate with the clinical presentation.

### Clinical Reference

1. Bancos I, Algeciras-Schimmich A, Woodmansee WW, et al. Determination of nadir growth hormone concentration cutoff in patients with acromegaly. *Endocr Pract.* 2013;19(6):937-945. doi:10.4158/EP12435.OR
2. Camacho-Hubner C. Assessment of growth hormone status in acromegaly: what biochemical markers to measure and how?. *Growth Horm IGF Res.* 2000;10 Suppl B:S125-S199
3. Nilsson AG. Effects of growth hormone replacement therapy on bone markers and bone mineral density in growth

- hormone-deficient adults. *Horm Res.* 2000;54 Suppl 1:52-57
4. Strasburger CJ, Dattani MT. New growth hormone assays: potential benefits. *Acta Paediatr Suppl.* 1997;423:5-11
  5. Okada S, Kopchick JJ. Biological effects of growth hormone and its antagonist. *Trends Mol Med.* 2001;7(3):126-132
  6. Veldhuis JD, Iranmanesh A. Physiological regulation of the human growth hormone (GH)-insulin-like growth factor type I (IGF-I) axis: predominant impact of age, obesity, gonadal function, and sleep. *Sleep.* 1996;19(10 Suppl):S221-S224
  7. Melmed S. Pathogenesis and diagnosis of growth hormone deficiency in adults. *N Engl J Med.* 2019;380(26):2551-2562. doi:10.1056/NEJMra1817346
  8. Karbasy K, Lin DC, Stoianov A, et al. Pediatric reference value distributions and covariate-stratified reference intervals for 29 endocrine and special chemistry biomarkers on the Beckman Coulter Immunoassay Systems: a CALIPER study of healthy community children. *Clin Chem Lab Med.* 2016;54(4):643-657. doi:10.1515/cclm-2015-0558

## Performance

### Method Description

The assay is performed on the Beckman Coulter UniCel DXI 800. The Access Ultrasensitive hGH (human growth hormone) assay is a simultaneous one-step immunoenzymatic ("sandwich") assay. A sample is added to a reaction vessel along with polyclonal goat anti-hGH alkaline phosphatase conjugate and paramagnetic particles coated with mouse monoclonal anti-hGH antibody. The patient sample hGH binds to the monoclonal anti-hGH on the solid phase, while the goat anti-hGH-alkaline phosphatase conjugate reacts with a different antigenic site on patient sample hGH. After incubation in a reaction vessel, materials bound to the solid phase are held in a magnetic field while unbound materials are washed away. Then, the chemiluminescent substrate Lumi-Phos 530 is added to the vessel, and light generated by the reaction is measured with a luminometer. The light production is directly proportional to the concentration of hGH in the sample. The amount of analyte in the sample is determined from a stored, multi-point calibration curve. (Package insert: Access Ultrasensitive hGH Growth Hormone. Beckman Coulter Inc.; 08/2024)

### PDF Report

No

### Day(s) Performed

Monday through Friday, Sunday

### Report Available

1 to 3 days

### Specimen Retention Time

14 days

### Performing Laboratory Location

Mayo Clinic Jacksonville Clinical Lab

## Fees & Codes

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**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 account representative. For assistance, contact [Customer Service](#).

**Test Classification**

This test has been cleared, approved, or is exempt by the US Food and Drug Administration and is used per manufacturer's instructions. Performance characteristics were verified by Mayo Clinic in a manner consistent with CLIA requirements.

**CPT Code Information**

83003

**LOINC® Information**

Test ID	Test Order Name	Order LOINC® Value
HGH	Growth Hormone, S	2963-7

Result ID	Test Result Name	Result LOINC® Value
HGH	Growth Hormone, S	2963-7