PEDIATRIC ENDOCRINOLOGY SERVICES

Specialized assays and protocols
for **pediatric patients**

LabCorp

Endocrine Sciences' endocrinology services program include

- 60-day frozen serum and plasma specimen storage, allowing for add-on or repeat testing up to 2 months after the original blood draw date (available for assays performed at the Endocrine Sciences facility)
- Protocols to accommodate multiple specimens for stimulation testing and diagnostic profiles
  - Quantitative specimen volume analysis performed prior to testing to ensure sufficient specimen volume
  - Pediatric volumes available for many common tests
- Assays developed specifically to aid in the diagnosis of endocrine disorders common among pediatric patients
  - Methodologies, such as HPLC/MS-MS, to measure low and abnormal hormone levels
  - Some reference intervals are age-specific or by pubertal Tanner stages
  - Processes, including extraction, to purify specimens prior to testing
- Direct access to scientific experts who specialize in pediatric endocrinology
  - PhD-level scientists available to discuss assay methodologies
  - MD-level consultations available to discuss patient cases

Superior Service

- Endocrine hotline staffed by experienced client service representatives
- Quick reference guides of expected values and instructions for response testing
- Endocrinologist requisition and stimulation testing requisition for simplified ordering
- Flexible connectivity options for test ordering and result reporting
- Broad managed care coverage

Adrenal disease

State newborn screening programs for CAH may include testing for 17-hydroxyprogesterone (17-OHP). The Endocrine Society recommends confirmatory testing via HPLC/MS-MS to improve the accuracy of screening.[1] LabCorp offers comprehensive tests with unique features for adrenal diseases:

- 17-OHP by HPLC/MS-MS methodology for a more sensitive and specific confirmation of CAH[1]
- Established CAH profiles to distinguish 21-hydroxylase from other types of CAH deficiencies utilizing HPLC-MS/MS to test many adrenal steroids
- CAH genetic testing for patients with suspected 21-hydroxylase gene mutations
- ACTH response guide in the Endocrine Syllabus that includes 0 minute and 60 minute post-ACTH stimulation reference intervals to help distinguish various types of enzyme deficiencies

Reproductive and gonadal disorders

- Stimulation testing requisition that simplifies ordering of complex stimulation combinations
- Results for many gonadal hormones include reference intervals by pubertal development (Tanner) stages, which are useful in evaluating patients with precocious puberty
- Electrochemiluminescence (ECL) and HPLC/MS-MS methodologies capable of measuring low hormone levels
  - Pediatric luteinizing hormone (LH) by ECL measuring to levels of 0.017 mIU/mL
  - Pediatric follicle-stimulating hormone (FSH) by ECL measuring to levels of 0.005 mIU/mL
  - Testosterone by HPLC/MS-MS can measure levels as low as 2.5 ng/dL and meets the Centers for Disease Control and Prevention (CDC) standards
- Broad menu of genetic tests to help determine causes of reproductive dysfunction, such as CAH, Klinefelter syndrome, and Turner syndrome

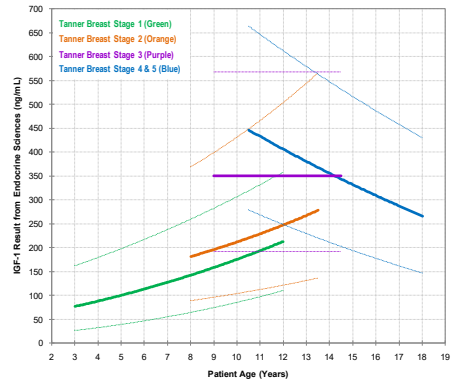
LabCorp provides the nation's premier laboratory services for the endocrinology specialist. Through the integration of regional laboratory testing and the expertise of Endocrine Sciences, a member of the LabCorp Specialty Testing Group, LabCorp offers a full-service solution designed to enhance the care and cost-effective treatment of pediatric patients.

Growth disorders

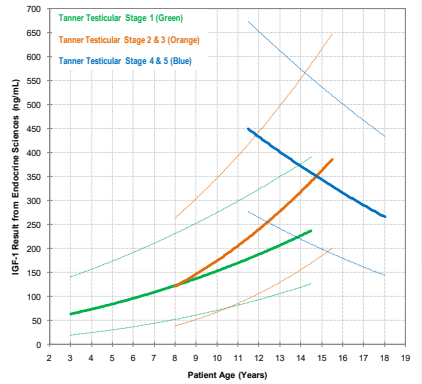
- Growth stimulation testing
- IGF-1, Pediatric with Z score
  - Novel approach to reporting IGF-1 that calculates Z score by comparing each patient's individual IGF-1 result to the reference interval for each pubertal Tanner stage, age, and gender
  - Z-Score is calculated using asymmetric curves with transformed data by Tanner stage*
  - Resulted for patients age 3 to 18 when age and gender are provided
  - IGF-1 methodology by extraction and RIA to reduce interference from binding proteins

*Examples of IGF-1 asymmetric curves with transformed data by Tanner stage[2]

Female IGF-1



Male IGF-1



- IGFBP-3 by RIA — Reference intervals with convenient mean and standard deviation ranges
- Exclusive SHOX DNA Dx® uses PCR and sequencing to identify genetic defects in the short stature homeobox-containing (SHOX) gene
- Genetic tests to aid in the diagnosis of other causes of short stature, including Turner syndrome and Prader-Willi syndrome

Mineral and bone metabolism issues

- Testing for minerals and bone metabolites, as well as parathyroid-related hormones and peptides
- A comprehensive menu of 25-hydroxy vitamin D and 1,25-dihydroxy vitamin D testing, including fractionated testing evaluations by HPLC/MS-MS for both 25-hydroxy and 1,25-dihydroxy vitamin D_2 and vitamin D_3

Thyroid disease

- Testing for hypothyroidism, including thyroid-stimulating hormone (TSH), thyroxine (T_4), triiodothyronine (T_3), free thyroxine (free T_4) by equilibrium dialysis and HPLC/MS-MS, and thyroxine-binding globulin (TBG)
- Testing for Graves disease, including TSH receptor antibodies, thyroid-stimulating immunoglobulin (TSI), antithyroglobulin antibodies (anti-Tg), and antithyroid peroxidase antibodies (anti-TPO)

Diabetes

- Diabetes autoimmune antibodies and antipancreatic islet cell testing that can assist with classification of type 1 diabetes
- Additional autoimmune testing for celiac disease and autoimmune thyroid diseases common in patients with type 1 diabetes[3]
- MODY genetic testing to assist in differentiating MODY from other forms of diabetes

Pediatric Endocrinology Test List

Test numbers below may be used when ordering through a LabCorp account. Refer to the online test menu at **www.LabCorp.com** for additional assays and test numbers for stimulation testing.

Congenital Adrenal Hyperplasia (CAH) and Other Adrenal Diseases

Test No.	Test Name
500171*	11-Deoxycortisol LC/MS-MS
504683	11-oxo-Androgens Panel
140715*	17-Hydroxypregnenolone, Mass Spectrometry
500163*	17-OH progesterone, LCMS
504045*	21-Deoxycortisol, LC/MS
500467*	Aldosterone LC/MS
500768*	CAH 21-Hydroxylase (CYP21) Mutation
501568*	Congenial Adrenal Hyperplasia (CAH) Pediatric Profile 1 – 21-Hydroxylase Deficiency Screen (androstenedione, cortisol, DHEA, 17-OH progesterone, testosterone)
500175*	Congenital Adrenal Hyperplasia (CAH) Pediatric Profile 6 – Comprehensive Screen (androstenedione, 11-desoxycortisol (specific S), cortisol, DHEA, deoxycorticosterone, 17-OH pregnenolone, progesterone, 17-OH progesterone, testosterone)
500166*	Congenital Adrenal Hyperplasia (CAH) Pediatric Profile 7 – Treatment (androstenedione, 17-OH progesterone, testosterone)
500154*	Cortisol, LC/MS
500156*	Dehydroepiandrosterone (DHEA), serum, by LCMS
500138*	Deoxycorticosterone (DOC)
140707*	Pregnenolone, Mass Spectrometry
500167*	Progesterone, LC/MS
500458*	Renin activity, plasma, RIA
500159*	Testosterone, total, women, children, and hypogonadal males by LCMS

Reproductive and Gonadal Disorders, including Precocious and Delayed Puberty

Test No.	Test Name
500171*	11-Deoxycortisol LC/MS-MS
504683	11-oxo-Androgens Panel
140715*	17-Hydroxypregnenolone, Mass Spectrometry
500163*	17-OH progesterone, LCMS
500152*	Androstenedione, LC/MS, Serum or Plasma
511035	Chromosome Analysis, Whole Blood (Constitutional)
500768*	Congenital Adrenal Hyperplasia (CAH) 21-Hydroxylase (CYP21) Mutation
500154*	Cortisol, LC/MS
500161*	DHEA Sulfate, LC/MS-MS
500142*	Dihydrotestosterone (DHT)
500108*	Estradiol, LC/MS
502280*	Follicle-stimulating Hormone (FSH), Pediatric
004416	Human Chorionic Gonadotropin (hCG), β-Subunit, Quantitative, Serum
502286*	Luteinizing Hormone, Pediatric
500159*	Testosterone, total, women, children, and hypogonadal males by LCMS

Growth Disorders, including Growth Hormone Deficiency, Primary IGF-1 Deficiency, & Idiopathic Short Stature

Test No.	Test Name
511210	Angelman and Prader-Willi Syndromes, DNA Analysis
511035	Chromosome Analysis, Whole Blood (Constitutional)
500632*	Growth Hormone, RIA
503660*	IGF-1, Pediatric with Z score
500644*	IGFBP-3, RIA
500110*	SHOX, DHPLC

References

1. Speiser PW, Azziz R, Baskin LS, Ghizzoni L, Hensle TW, Merke DP, Myer-Bahlburg HFL, Miller WL, Montori VM, Oberfield SE, Ritzen M, White PC. Congenital Adrenal Hyperplasia Due to Steroid 21-hydroxylase Deficiency: An Endocrine Society Clinical Practice Guideline. *J Clin Endocrinol Metab.* Sept 2010; 95(9):4133-4160.
2. Internal data on file. Endocrine Sciences, 2012.
3. American Diabetes Association. Standards of Medical Care in Diabetes – 2011. *Diabetes Care.* Jan 2011; 34(1):S11-S48.

Mineral Metabolism Disorders

Test No.	Test Name
001107	Alkaline Phosphatase
081091	Calcitriol (1,25 di-OH Vitamin D)
500600*	Calcitriol (1,25 di-OH Vitamin D), fractionated D_2 and D_3 by LCMS
001016	Calcium
001370	Creatinine
001537	Magnesium
015610	Parathyroid Hormone (PTH), Intact
001024	Phosphorus
081950	Vitamin D, 25-Hydroxy
504115*	Vitamin D, 25-Hydroxy, Fractionated, Mass Spectrometry

Thyroid Disorders, including Hypothyroidism and Graves Disease

Test No.	Test Name
070034	Iodine, Serum or Plasma
504008	MEN2:RET Gene Sequencing
006685	Thyroglobulin Antibody
006676	Thyroid Peroxidase (TPO) Antibodies
004259	Thyroid-stimulating Hormone (TSH)
140749	Thyroid-stimulating Immunoglobulin (TSI)
001149	Thyroxine (T_4)
501902*	Thyroxine (T_4), Free, Dialysis/Mass Spectrometry
001974	Thyroxine (T_4), Free, Direct
001735	Thyroxine-binding Globulin (TBG), Serum
002188	Triiodothyronine (T_3)
010389	Triiodothyronine (T_3), Free
503600*	Triiodothyronine (T_3), Free, Dialysis and LC/MS-MS
500538*	TSH Receptor Antibody (TBII), RRA

Type 1 Diabetes and Common Autoimmune Conditions

Test No.	Test Name
160721	Antipancreatic Islet Cells
164700	Celiac Disease Pediatric Screen with Reflex (includes tissue transglutaminase IgA, total immunoglobulin A, tissue transglutaminase IgG; reflex to total IgA and/or tTG IgG)
504050*	Diabetes Autoimmune Profile (includes ICA-512/IA-2 antibodies, GAD-65 antibodies, insulin antibodies and ZNT8 antibodies)
006685	Thyroglobulin Antibody
504603	Maturity-Onset Diabetes of the Young (MODY) Genetic Profile
006676	Thyroid Peroxidase (TPO) Antibodies

**Testing performed at Endocrine Sciences*

Experienced client services team

Specialized Endocrine Hotline--**877-436-3056**-- available for technical assistance or add-on requests

Specialized test request forms

Endocrinologist services requisition and stimulation testing requisition simplify test ordering

Flexible connectivity solutions

- LabCorp Link™ for Web-based test ordering and result delivery
- Connectivity with more than 700 vendor interfaces

Comprehensive coverage

- Approved vendor for various national hospital group purchasing organizations (GPOs)
- Broad participation in managed care and insurance plans

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Please contact your local account representative for more information, or visit **www.LabCorp.com**.