Courtagen
DIAGNOSTICS LABORATORY

Courtagen's devSEEK®

Neuro-development

Test for Known Genetic Causes of DD, ID, ASD

Next Generation Sequencing panel for the analysis of genes known to be causative of neurodevelopmental disorders including Developmental Delay, Intellectual Disability, and Autism Spectrum Disorders

Courtagen's devSEEK® Next Generation Sequencing Panels enables the rapid analysis of genes most commonly associated with genetic syndromes as well as non-syndromic forms of developmental delay (DD), intellectual disability (ID), and autism spectrum disorders (ASD).

The neurodevelopmental disorders of DD, ID, and/or ASD are diverse with a wide range of symptoms and severity. Multiple lines of evidence support the strong role of genetics in the etiology of these disorders.

The devSEEK or devSEEK Triome panels can be combined with the devACT panel for additional analysis of metabolic disorders.

devACT® Clinical Management Panel

Unique test to screen genes that impact treatment or indicate follow up testing (e.g., inborn errors of metabolism)

devSEEK® & devSEEK® Triome Neurodevelopmental Disorders

Diagnostic tests to identify known genetic causes of DD,ID,ASD

devSEEK® Triome™ (1,119 genes): Designed to provide the most complete picture, the devSEEK Triome panel uses powerful trio analysis, by fully sequencing the parent's samples along with the patient, to enable extensive genetic analysis and clinical interpretation of an expanded selection of genes associated with developmental delay, and intellectual disability, and many additional genes associated with autism spectrum disorder.

devSEEK® (237 genes): Designed to provide a thorough view, the devSEEK panel enables genetic analysis and clinical interpretation of a wide range of genes associated with developmental delay, intellectual disability and autism spectrum disorder phenotypes. Additional analysis of exon-sized (and larger) deletion and duplication variants in 28 genes is available as an add-on.

Indications for Testing

Primary Indications
- Autism Spectrum Disorder
- Developmental delay
- Intellectual disability
- Cognitive impairment

Secondary Indications (examples)
- Short Stature
- Ataxia
- Dysmorphic features
- Brain malformations
- Seizures
- Cardiomyopathy
- Hearing impairment
- Visual impairment
- Muscular control: e.g. hypotonia, hypertonia, tremors, hyperreflexia, atrophy
- Failure to thrive

Courtagen provides saliva DNA specimen collection kits at no charge. Questions? Contact our Patient Advocates.

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Test Overview

This test was designed to sequence the exons and canonical splice sites (+/-1,2) of a panel of genes associated with developmental delay, intellectual disability and autism spectrum disorders. Genomic DNA is extracted from the submitted sample (typically saliva), and captured with an inversion probe method for the genes specific to this panel. The captured targets are sequenced on the Illumina MiSeq sequencing system with 250bp paired-end reads. Panel specific sequencing coverage, specificity, and sensitivity are listed below:

	devSEEK Triome	devSEEK
Mean depth of coverage:	>400	>400
Specificity:	98.8%	99%
Sensitivity:	99.9%	98.3%

Courtagen's Unmatched Customer Support

Turn Around Time: 4-6 weeks. Results are delivered in weeks, not months.

Saliva Sample: DNA for sequencing is reliably extracted from a single saliva sample. No blood draw or muscle biopsy required; however blood and muscle tissue are accepted. No charge saliva kits are provided, no charge phlebotomy services are offered.

Insurance Assistance: Courtagen works with patients, physicians, and insurance carriers to pre-approve each test. Courtagen will bill the insurance company and is willing to handle an appeal process as needed.

Courtagen Care Financial Assistance Program: Provides financial assistance to patients based on demonstrated financial need. A qualified applicant may be asked to contribute between $0 and a maximum cost sharing of $200 depending on determination of financial need.

Online Portal: A secure physician online portal is available for ordering genetic tests and accessing patient reports when completed.

Genetic Counselors: Available to address your questions regarding Courtagen test results. Contact us at clinical@courtagen.com.

Clinical Experience: Courtagen's Medical Director, Laboratory Director, and variant science team have over 25 years of experience in the treatment and genetic interpretation of neurological and metabolic disorders.

Reports: Utilizing Courtagen's customized ZiPhyr® informatics pipeline and thorough clinical evaluation, each report is provided in a concise format with interpretation and recommendations for consideration.

Data and DNA Security: Advanced IT solutions safeguard patient records and financial information. In the laboratory, Courtagen de-identifies patient and test records and uses the proprietary method of DREAM PCR to provide exceptional lab decontamination.

Required forms

Courtagen Test Requisition (completed and signed by ordering clinician)

Signed Patient Consent (on the Courtagen Test Requisition or Consent Form provided in the saliva kit)

Photocopy front & back of all insurance cards (including subscriber date of birth)