JANUARY 2022

THE DATA DRIVEN POINT OF VIEW

A Genetics, Genomics & Precision Medicine Newsletter

TRENDING TOPIC:

New York Times Article

"When They Warn of Rare Disorders, These Prenatal Tests Are Usually Wrong"

Published on 1/1/2022

NO FDA REGULATION EXISTS FOR PRENATAL GENETIC TESTING

Lack of FDA regulation results in marketing claims from prenatal genetic testing labs that are misleading for providers and patients.

The recent article published in The New York Times references major CLIA and CAP accredited labs providing prenatal screening tests with marketing materials and claims that are misleading to patients and can lead to unnecessary interventions when results are not communicated appropriately.

cgi Center for Genomic Interpretation

Ph. (801) 810-4097
contact@genomicinterpretation.org
https://www.genomicinterpretation.org/

IS DATA PUBLICLY AVAILABLE FROM YOUR CONTRACTED LABS SHOWING THE OVERALL ACCURACY OF PATIENT RESULTS?

NOT ALL LABS OR TESTING ARE CREATED EQUAL

"Some of the companies offer tests without publishing any data on how well they perform, or point to numbers for their best screenings while leaving out weaker ones."

*Is there **transparency** from your contracted labs?*

"Alberto Gutierrez, the former director of the FDA office that oversees many medical tests, reviewed marketing materials from three testing companies and described them as '**problematic**.'"

"There are **few restrictions** on what test makers can offer. The Food and Drug Administration often requires evaluations of how frequently other consequential medical tests are right and whether shortfalls are clearly explained to patients and doctors. But **the FDA does not regulate this type of test**."

"In interviews, **14** patients who got false positives said the **experience was agonizing**. They recalled frantically researching conditions they'd never heard of, followed by sleepless nights and days hiding their bulging bellies from friends. **Eight** said they **never received any information** about the possibility of a false positive, and **five** recalled that their **doctor treated the test results as definitive**."

Transparency in marketing and reporting practices are vital for appropriate follow-up actions for prenatal screening. Let CGI help to identify accurate and transparent laboratories that provide providers and patients with the truth.

cgi Center for Genomic Interpretation

Ph. (801) 810-4097
contact@genomicinterpretation.org
https://www.genomicinterpretation.org/

SPECIAL PROJECT AVAILABILITY

DOES LAB MARKETING MATCH ACTUAL TEST PERFORMANCE?

Center for Genomic Interpretation can assist you with:

1. Reviewing basic evidence. Center for Medicare Services (CMS) requires the data be provided in order to receive reimbursement, but this data is not shared by CMS. You can request this data directly from labs, then CGI will analyze it.

2. Does the actual lab data match the marketing materials distributed to healthcare providers and patients?

BENEFITS OF PROJECT:

- Consistency of more accurate results for plan members
- Ensure that contracted labs are aligning marketing to actual results

OUR COMMITMENT:

- RAPID TAT
- LOW COST EVALUATION

CONTACT US TODAY!

cgi Center for Genomic Interpretation

Ph. (801) 810-4097
contact@genomicinterpretation.org
https://www.genomicinterpretation.org/

Who is CGI? How can they help us?

The Center for Genomic Interpretation (CGI) is an independent 501(c)(3) nonprofit organization with the mission to save and improve lives through encouraging careful stewardship of clinical genetics, genomics, and precision medicine. Too frequently precision medicine goals are unknowingly thwarted by inaccurate or ineffective genetic or genomic testing. CGI's clinical genetic and genomic industry experts facilitate the realization of value among the confusion of precision medicine. To assist decision makers in making wise choices about genetic and genomic tests, CGI offers a range of uniquely helpful services through CGI's ELEVATEGENETICS initiative. CGI also works with payers and other stakeholders through special projects.

ELEVATEGENETICS

LANDSCAPE | **BRILLIANT** | **DECLARE** | **CLARITY**

Providing the metrics needed by stakeholders to identity the most accurate and clinically efficacious genetic and genomic tests

LANDSCAPE - Evaluates the technical landscape of genetic/genomic tests to determine if the billing codes being used are fraudulent or misrepresenting technical capability. (Pairs well with BRILLIANT and third party CPT code specificity analyses).

BRILLIANT - For next generation DNA sequencing genetic/genomic tests (NGS). Assesses if a laboratory has correctly represented what types of genetic variants/mutations their DNA sequencing tests can detect and characterizes the stringency of each laboratory's genetic variant classification approaches for unique tests.

DECLARE - A standardized online survey which guides laboratories through answering questions about quality, accuracy and clinical efficacy for their tests that go far beyond the requirements of CLIA and CAP accreditation. Laboratory answers for unique tests can be verified by CGI through other ELEVATEGENETICS services and special projects.

CLARITY - Evaluates if a laboratory has used sufficient evidence to classify variants as therapeutic targets. False positive variant classifications are common, which often lead to inappropriate downstream healthcare.

cgi Center for Genomic Interpretation

Ph. (801) 810-4097
contact@genomicinterpretation.org
https://www.genomicinterpretation.org/
Follow us on LINKEDIN