

*Helping to adjust treatment
of diabetic patients and
identify predisposition
for diabetes in
relatives of patients.*

Monogenic Diabetes (MODY) Evaluation



Testing performed under license from



Correlagen Diagnostics, Inc.
www.correlagen.com



Testing You Can Count On.

Athena Diagnostics offers testing for mutations in five genes associated with MODY.

- MODY is a monogenic form of diabetes with an autosomal dominant mode of inheritance:¹
 - Mutations in any one of several transcription factors or in the enzyme glucokinase lead to insufficient insulin release from pancreatic β -cells, causing MODY.
 - Different subtypes of MODY are identified based on the mutated gene.
- Originally, diagnosis of MODY was based on presence of non-ketotic hyperglycemia in adolescents or young adults in conjunction with a family history of diabetes.
- However, genetic testing has shown that MODY can occur at any age and that a family history of diabetes is not always obvious.^{2,3} MODY is estimated to account for 1-5% of all cases of diabetes in the US.¹
 - MODY in young children or older adults may be confused with pre-ketotic type 1 diabetes or type 2 diabetes, respectively.^{2,3}
 - MODY2, which is often first detected during pregnancy, may be mistaken for gestational diabetes.⁴
- Treatment and prognosis depend on the MODY subtype and may differ from those for other forms of diabetes (see Figure 1).^{3,5}
- Since MODY is inherited in an autosomal dominant manner, blood relatives of MODY patients are at an increased risk for diabetes.

Why genetic testing?

Genetic testing for mutations associated with MODY1, MODY2, MODY3, MODY4, or MODY5

- Permits fast and accurate diagnosis of MODY in about 85% of affected individuals.
- Can distinguish between common subtypes of MODY, facilitating selection of the most appropriate treatment.
- Enables family screening for MODY, promoting timely detection of hyperglycemia in family members of MODY patients.

Indications for testing:

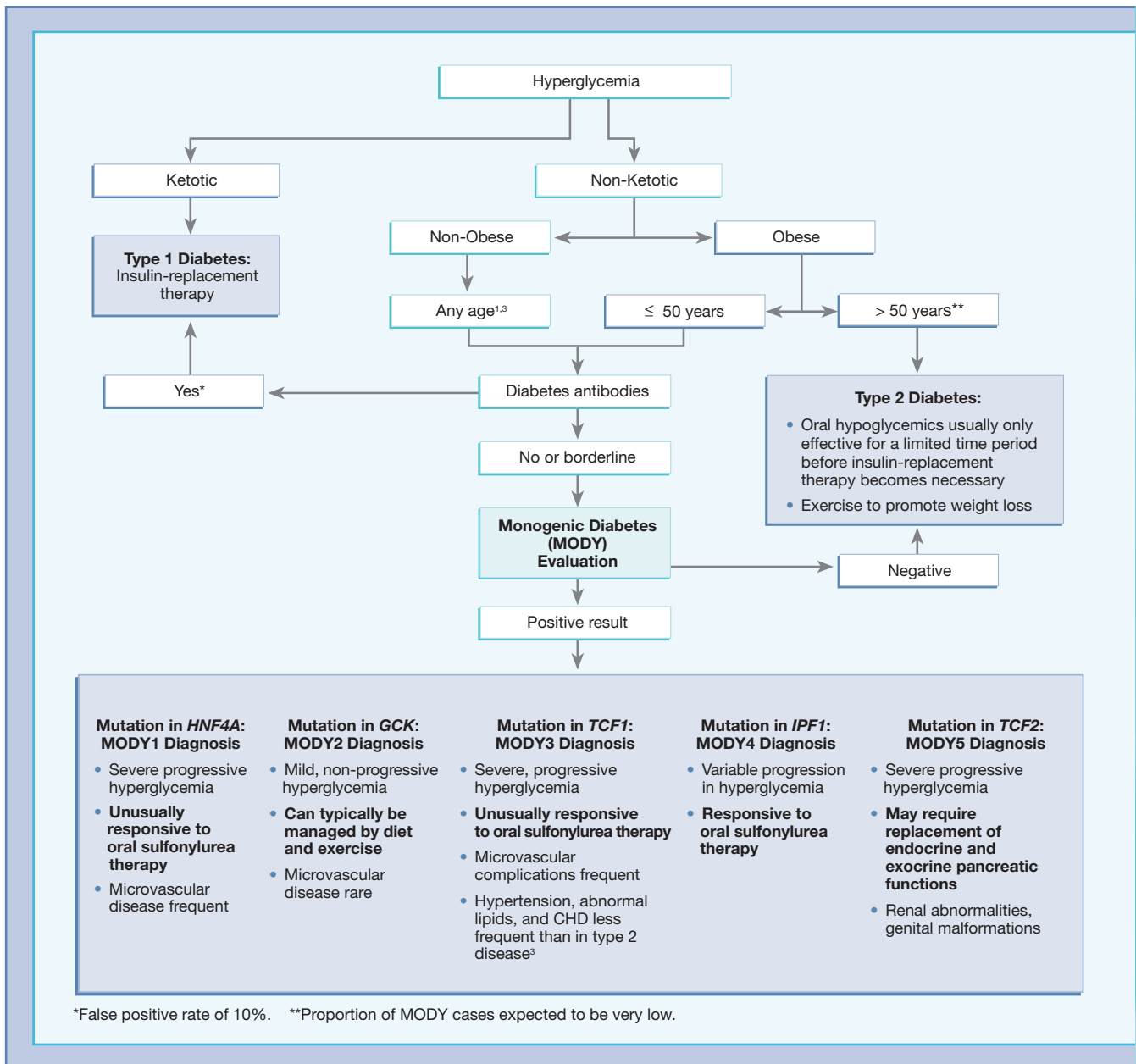
- Non-ketotic insulin-sensitive hyperglycemia in individuals of any age (see Figure 1)
- Family history of MODY

References: 1. Fajans SS, et al., (2001) *N Engl J Med* 345:971-80. 2. Frayling TM, et al., (2001) *Diabetes* 50 Suppl 1:S94-100. 3. Timsit J, et al., (2005) *Treat Endocrinol* 4:9-18. 4. Ellard S, et al., (2000) *Diabetologia* 43:250-3. 5. Stride A & Hattersley AT (2002) *Annals of Medicine* 34:207-16.

For a brief review on MODY, please visit www.athenadiagnostics.com/DR

A genetic test can confirm a diagnosis of MODY and help choose appropriate therapy.

Figure 1: An approach to diagnosing MODY



For complete ordering information, please see the reverse side.

Monogenic Diabetes (MODY) Evaluation

Typical Presentation: Non-ketotic hyperglycemia in non-obese individuals of any age

Indications for Testing:

- Non-ketotic insulin-sensitive hyperglycemia in individuals of any age
- Family history of MODY

TEST DETAILS

Test Code: 839

Test Includes: *HNF4A* (MODY1) DNA Sequencing Test #831
GCK (MODY2) DNA Sequencing Test #832
TCF1 (MODY3) DNA Sequencing Test #833
IPF1 (MODY4) DNA Sequencing Test #834
TCF2 (MODY5) DNA Sequencing Test #836

Test Turnaround: 14-21 days

TECHNICAL INFORMATION

Methodology: Polymerase Chain Reaction (PCR), DNA sequencing of entire protein coding regions of genes

Patents: United States Patents Nos. 6,187,533, 5,541,060, and 6,274,310

SHIPPING CONSIDERATIONS

Specimen Type: Whole blood

Volume: 10 mL (pediatric minimum: 2 mL)

Collection Tube: Yellow or lavender top

Stability: Hemolysis may compromise DNA recovery and integrity after 48 hrs

Storage Conditions: For short periods (until shipped) at 4°C

Shipping Conditions: Overnight at room temperature (specimen arrival must be less than 24 hrs after collection); ship Monday through Thursday only

To order the Monogenic Diabetes (MODY) Evaluation (Test #839), call Athena Diagnostics' Customer Service Representatives at:

800-394-4493 x2



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