



血糖检测及 糖代谢紊乱的实验诊断

南方医院检验科 张鹏

nfyyzp@126.com





主要内容:

- 一、糖代谢紊乱的临床检验指标
- 二、糖代谢紊乱的实验诊断





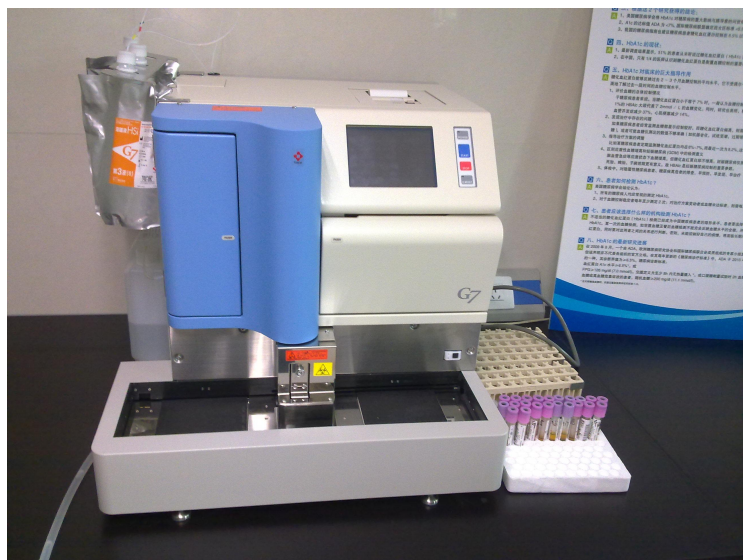
一、糖代谢紊乱的临床检验指标

- 1、空腹血糖 (FPG)
- 2、口服葡萄糖耐量试验 (OGTT)
- 3、糖化血红蛋白 (HbA1C)
- 4、糖化血清蛋白 (果糖胺)
- 5、胰岛素与C肽
- 6、谷氨酸脱羧酶抗体 (GAD-Ab)
- 7、酮体检测
- 8、尿微量白蛋白 (AlbU)











1、空腹血糖（fasting plasma glucose, FPG）

参考范围（reference interval）：

3.9~6.1mmol/L





- 血糖升高的临床意义:

1. 糖尿病
2. 内分泌疾病
3. 应激性高血糖
4. 药物影响
5. 饱食、高糖饮食
6. 剧烈运动或精神紧张





- 血糖降低的临床意义：
 1. 血中胰岛素升高或降糖药使用过量
 2. 缺乏抗胰岛素的激素
 3. 糖原储存缺乏的疾病
 4. 急性酒精中毒
 5. 妊娠期
 6. 饥饿





血糖检测时的注意事项

Guidelines and Recommendations for Laboratory Analysis in the Diagnosis and Management of Diabetes Mellitus

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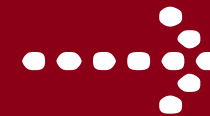
Recommendation: To minimize glycolysis, a tube containing a rapidly effective glycolytic inhibitor such as granulated citrate buffer should be used for collecting the sample. If this cannot be achieved, the sample tube should immediately be placed in an ice-water slurry and subjected to centrifugation to remove the cells within 15 to 30 min. Tubes with only enolase inhibitors such as sodium fluoride should not be relied on to prevent glycolysis. B (moderate)

ANALYTICAL CONSIDERATIONS

Preanalytical.

Recommendation: Blood for fasting plasma glucose analysis should be drawn in the morning after the subject has fasted overnight (at least 8 h). B (low)





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Recommendation: Based on biological variation, glucose measurement should have analytical imprecision $\leq 2.4\%$, bias $\leq 2.1\%$ and total error $\leq 6.1\%$. To avoid misclassification of individuals, the goal for glucose analysis should be to minimize total analytical error and methods should be without measurable bias. B (moderate)





新进展--空腹血糖参考范围的重新确定

3.9-6.1mmol/L → 3.9-5.6mmol/L

0-12y : 3.3-5.6mmol/L

>12y : 4.1-5.9mmol/L





新进展--关于尿糖在DM诊断中的地位的变化

Guidelines and Recommendations for Laboratory Analysis in the Diagnosis and Management of Diabetes Mellitus

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Urine Glucose

Recommendation: Urine glucose testing is not recommended for routine care of patients with diabetes mellitus. B (low)





2、口服葡萄糖耐量实验 (oral glucose tolerance test , OGTT)

- 0h, 0.5h, 1h, 1.5h, 2h, 3h
- in case of...





Perform of OGTT

- 1、 forbid food, tobacco, alcohol and coffee **8hrs** before the test





2、 draw blood sample at empty stomach and have **FPG** examined





3、 Glucose **75g** for oral use, start timing.





- 4、 Draw blood sample at 0.5h, 1h, 2h post-glucose load, and have plasma glucose examined immediately





We are using OGTT results to diagnose:

- 1、 diabetes mellitus(DM)
- 2、 impaired fasting glucose(IFG)
- 3、 impaired glucose tolerance(IGT)





新进展--OGTT试验对患者准备的新要求

- 经典要求:

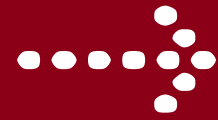
- ① 试验前8h禁烟, 酒, 咖啡, 禁食
- ② 空腹抽血
- ③ 口服Glucose 75g, 计时
- ④ 0.5h, 1h, 1.5h, 2h, 3h时抽血, 马上送检



- 新要求:

- ① 试验前**8-14h**禁烟, 酒, 咖啡, 禁食
- ② 空腹抽血
- ③ **10min后**口服Glucose 75g, 计时
- ④ **1h, 2h**时抽血, 马上送检





3、糖化血红蛋白检测(HbA1C)

- Hb β 链末端氨基酸与葡萄糖进行缩合反应形成HbA_{1c}酮氨化合物，反应速度取决于血糖浓度及血糖与Hb的接触时间。
- 临床意义：HbA_{1c}反映抽血前1~2个月内血糖的平均水平，对鉴别糖尿病性高血糖和应激性高血糖有价值。可作为治疗监测和确定治疗方案的依据。
- 参考范围4~6%





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Screening/diagnosis.

Recommendation: Laboratory-based Hb A_{1c} testing can be used to diagnose

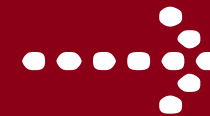
(a) diabetes, with a value $\geq 6.5\%$ (≥ 48 mmol/mol) diagnostic of diabetes, and

(b) prediabetes (or high risk for diabetes) with an Hb A_{1c} level of 5.7% to 6.4% (39 to 46 mmol/mol). An NGSP-certified method should be performed in an accredited laboratory. A (moderate)

Monitoring.

Recommendation: Hb A_{1c} should be measured routinely (usually every 3 months until acceptable, individualized targets are achieved and then no less than every 6 months) in most individuals with diabetes mellitus to document their degree of glycemic control. A (moderate)





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Monitoring/prognosis.

Recommendation: Routine measurement of plasma glucose concentrations in a laboratory is not recommended as the primary means of monitoring or evaluating therapy in individuals with diabetes. B (moderate)

control, rather than glucose concentration. Moreover, most clinicians use the recommendations of the ADA and other organizations which define a target Hb A_{1c} concentration as the goal for optimum glycemic control (25, 59).





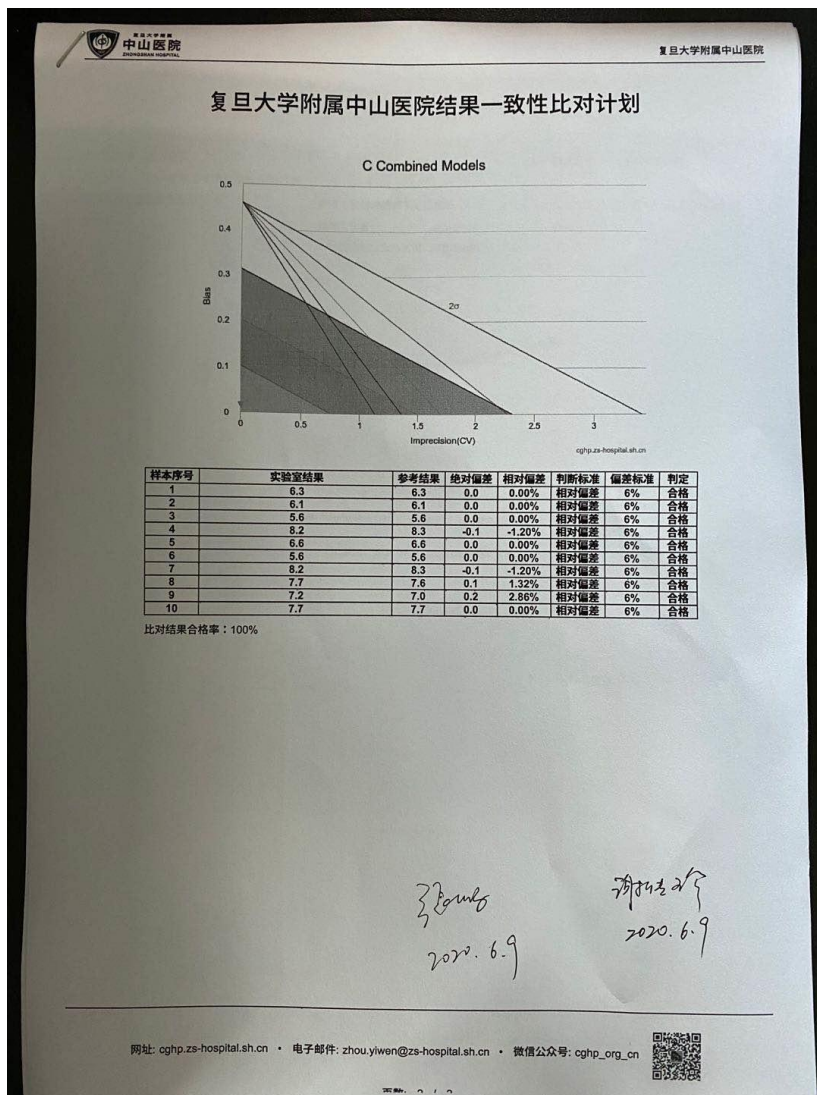
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Recommendation: Laboratories should use only Hb A_{1c} assay methods that are certified by the NGSP as traceable to the DCCT reference. The manufacturers of Hb A_{1c} assays should also show traceability to the IFCC reference method. GPP

NGSP : National Glycohemoglobin Standardization Program ,
<http://www.ngsp.org/>





Harmonizing Hemoglobin A_{1c} Testing

NGSP

A better A_{1c} Test means better diabetes care

Certificate of Traceability

Level I Laboratory Certification

This certifies that Department of Laboratory Medicine, Nanfang Hospital, Southern Medical University, using Roche cobas c 502 has participated in and successfully completed NGSP Level I Laboratory certification and is traceable to the **Diabetes Control and Complications Trial** Reference method. The comparison was performed with: University of Missouri SRL#9

The system evaluated was:

Instrument:	Calibrator Lot:	Application:
cobas c 502	175535	Gen.3 WB
Reagent Lot:	Calibrator Assigned Values:	HbA _{1c} /Hb*91.5+2.15
603033	0.138, 0.340, 0.665, 0.922, 1.256, 1.789 mmol/L HbA _{1c} ; 1.37, 7.38 mmol/L Hb	

Date of Certification: December 1, 2014 Certification Expires: December 1, 2015

NGSP Steering Committee Chair NGSP Network Coordinator SRL director/ supervisor





Recommendation: Laboratories should be aware of potential interferences, including hemoglobin variants that may affect Hb A_{1c} test results depending on the method used. In selecting assay methods, laboratories should consider the potential for interferences in their particular patient population. GPP

Recommendation: Hb A_{1c} measurements in individuals with disorders that affect red blood cell turnover may provide spurious (generally falsely low) results regardless of the method used and glucose testing will be necessary for screening, diagnosis, and management. GPP

Recommendation: Hb A_{1c} cannot be measured and should not be reported in individuals who do not have Hb A, e.g., those with homozygous hemoglobin variants, such as Hb SS or Hb EE; glycated proteins, such as fructosamine or glycated albumin, may be used. GPP





Guidelines and Recommendations for Laboratory Analysis in the Diagnosis and Management of Diabetes Mellitus

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Out-of-range specimens.

Recommendation: Laboratories should verify by repeat testing specimens with Hb A_{1c} results below the lower limit of the reference interval or greater than 15% (140 mmol/mol) Hb A_{1c}. GPP





新进展--糖化血红蛋白的新应用

- 经典应用：

HbA_{1c}反映
抽血前**1~2个
月内**血糖的平
均水平，对鉴
别糖尿病性高
血糖和应激性
高血糖有价值。



- 新应用（2009ADA）：

将HbA_{1c}>6.5%作为2型糖
尿病的**诊断标准**

将HbA_{1c}≤7.0%作为2型糖
尿病患者的**血糖控制目
标值**



- 最新进展（2019ACP）：

将2型糖尿病患者的血糖控
制目标值**放宽到7%-8%
之间**





4、糖化血清蛋白检测

- 临床意义同HbA_{1c}，但反映抽血前**1个月内**的血糖水平。
- 参考范围：1.6-2.1mmol/L





新进展--糖化血清蛋白检测的标准化

糖化血清蛋白



糖化白蛋白





Guidelines and Recommendations for Laboratory Analysis in the Diagnosis and Management of Diabetes Mellitus

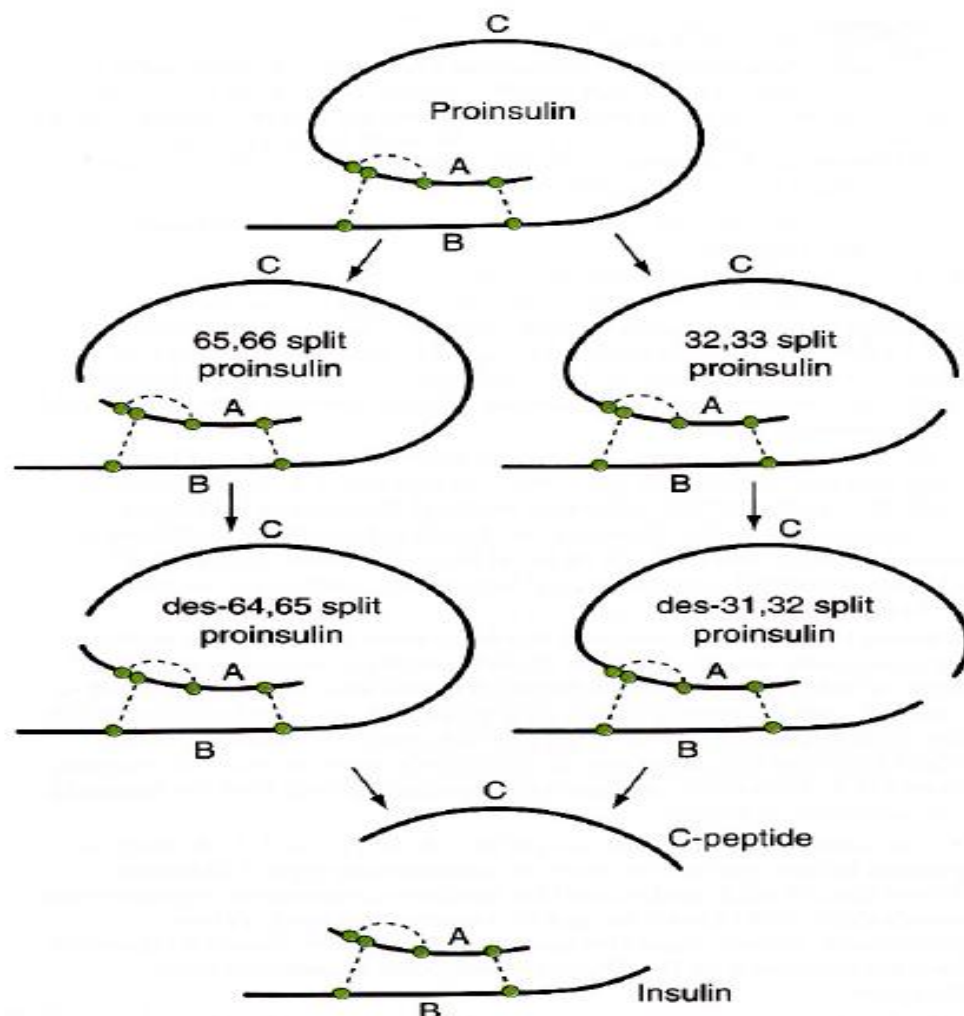
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Recommendation: Assays of other glycosylated proteins, such as fructosamine or glycosylated albumin, may be used in clinical settings where abnormalities in red blood cell turnover, hemoglobin variants, or other interfering factors compromise interpretation of Hb A_{1c} test results, although they reflect a shorter period of average glycemia than Hb A_{1c}. GPP





5、血清胰岛素与C肽的测定



- C肽：胰岛素产生过程的一种中间产物





- 临床意义:

- 1、正常人: 胰岛素, C肽释放入血量与血糖平行。
- 2、DM病人: 由于要经常使用外源性的胰岛素血清C肽的水平往往与血糖不平行。





新进展--血清C肽检测提上日程

- C肽的优点：不受外源性胰岛素的干扰，不受胰岛素抗体的干扰
- C肽的缺点：半衰期是胰岛素的10倍，不能反应胰岛素的急剧变化。





新进展--血清胰岛素与C肽检测不建议在糖尿病患者中常规使用

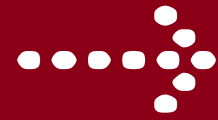
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Recommendation: In most people with diabetes or risk for diabetes or cardiovascular disease, routine testing for insulin or proinsulin is not recommended. These assays are useful primarily for research purposes. B (moderate)

Recommendation: Although differentiation between type 1 and type 2 diabetes can usually be made based on the clinical presentation and subsequent course, C-peptide measurements may help distinguish type 1 from type 2 diabetes in ambiguous cases, such as individuals who have a type 2 phenotype but present in ketoacidosis. B (moderate)

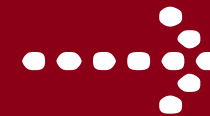




6、谷氨酸脱羧酶抗体（GAD-Ab）

- **GAD**是自身抗原介导的免疫反应所引起胰岛B-细胞破坏的始动靶抗原，**GAD-Ab**是糖尿病前期较特异的免疫指标。
- 临床意义：
可作为1型糖尿病的预测，普查可发现1型糖尿病的高危人群和个体
从2型糖尿病患者中鉴别迟发型1型患者





Guidelines and Recommendations for Laboratory Analysis in the Diagnosis and Management of Diabetes Mellitus

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Recommendation: Standardized islet autoantibody tests are recommended for classification of diabetes in adults in whom there is phenotypic overlap between type 1 and type 2 diabetes and uncertainty as to the type of diabetes. GPP

Recommendation: Islet autoantibodies are not recommended for routine diagnosis of diabetes. B (low)





7、酮体检测

- 酮体有效成分检测主要用于糖尿病酮症酸中毒的实验诊断。
- β -羟丁酸，乙酰乙酸，丙酮。





Guidelines and Recommendations for Laboratory Analysis in the Diagnosis and Management of Diabetes Mellitus

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Recommendation: Individuals who are prone to ketosis (those with type 1 diabetes, history of diabetic ketoacidosis [DKA], or treated with sodium-glucose co-transporter-2 (SGLT-2) inhibitors should measure ketones in urine or blood if they have unexplained hyperglycemia or symptoms of ketosis (abdominal pain, nausea), and implement sick day rules and/or seek medical advice if urine or blood ketones are increased. B (moderate)

Recommendation: Specific measurement of β -hydroxybutyrate (β OHB) in blood should be used for diagnosis of DKA and may be used for monitoring during treatment of DKA. B (moderate)





8、尿微量白蛋白测定(AlbU)

- 尿微量白蛋白反应肾小球损伤情况。
- 但尿量多少是影响尿微量白蛋白浓度的主要干扰因素，临床通常采用测24h尿微量白蛋白总量（参考范围0-30mg/24h）的方法排除干扰。





Guidelines and Recommendations for Laboratory Analysis in the Diagnosis and Management of Diabetes Mellitus

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Recommendation: Annual testing for albuminuria should begin in pubertal or post-pubertal individuals

5 years after diagnosis of type 1 diabetes and at the time of diagnosis of type 2 diabetes, regardless of treatment. A (high)





新进展--尿微量白蛋白测定排除尿量干扰的新方法

- 经典方法：

测24h尿Alb总量
(参考范围0-
30mg/24h)



- 新方法：

用尿肌酐排除尿量的干扰，
测量尿Alb/尿CR比值
(参考范围0-30mg/g)。





二、糖代谢紊乱的实验室诊断





Diagnostic Criteria

	0h	2h	casual
Normal	4.1 ~ 5.9	<7.8	<11.1
DM	≥ 7.0	≥ 11.1	≥ 11.1
IFG	5.9 ~ 7.0		
IGT		7.8 ~ 11.1	

Consider the
clinical features





Three groups of numbers to remember

- 4.1 5.9
- 7.0 11.1
- 5.9 7.8





Clinical Cases

1、 female, 32yrs, presented with “burning mouth”

0h	0.5h	1h	2h
6.2	11.7	15.2	15.0





2、 male, 41yrs

0h	0.5h	1h	2h
6.0	9.5	10.8	8.5





3、 female, 45yrs

0h	0.5h	1h	2h
5.0	8.6	7.7	8.8





新进展--DM的诊断

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Table 4 ^f . Criteria for the diagnosis of diabetes. ^a
1. Hb A _{1c} \geq 6.5% (48 mmol/mol) ^b
or
2. FPG \geq 7.0 mmol/L (126 mg/dL) ^c
or
3. 2-h Plasma glucose \geq 11.1 mmol/L (200 mg/dL) during an OGTT ^d
or
4. In a patient with classic symptoms of hyperglycemia or hyperglycemic crisis, a random plasma glucose \geq 11.1 mmol/L (200 mg/dL) ^e





新进展--GDM的诊断

Guidelines and Recommendations for Laboratory Analysis in the Diagnosis and Management of Diabetes Mellitus

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Recommendation: All pregnant women with risk factors for diabetes should be tested for undiagnosed prediabetes and diabetes at the first prenatal visit using standard diagnostic criteria. A (moderate)

Recommendation: All pregnant women not previously known to have diabetes should be evaluated for GDM at 24 to 28 weeks of gestation. A (high)





Table 7. Screening for and diagnosis of GDM.^{a,b}

1-step strategy

Perform a 75-g OGTT, with plasma glucose measurement when patient is fasting and at 1 and 2 h, at 24 to 28 weeks of gestation in women not previously diagnosed with diabetes.

The OGTT should be performed in the morning after an overnight fast of at least 8 h.

The diagnosis of GDM is made when any of the following plasma glucose values are met or exceeded:

- fasting: 92 mg/dL (5.1 mmol/L)
- 1 h: 180 mg/dL (10.0 mmol/L)
- 2 h: 153 mg/dL (8.5 mmol/L)

2-step strategy

Step 1: Perform a 50-g GLT (nonfasting), with plasma glucose measurement at 1 h, at 24 to 28 weeks of gestation in women not previously diagnosed with diabetes.

If the plasma glucose level measured 1 h after the load is ≥ 130 , 135, or 140 mg/dL (7.2, 7.5, or 7.8 mmol/L, respectively)^c, proceed to a 100-g OGTT.

Step 2: The 100-g OGTT should be performed when the patient is fasting.

The diagnosis of GDM is made when at least 2^d of the following 4 plasma glucose levels (measured fasting and at 1, 2, and 3 h during OGTT) are met or exceeded [Carpenter–Coustan criteria (243)]:

- Fasting: 95 mg/dL (5.3 mmol/L)
- 1 h: 180 mg/dL (10.0 mmol/L)
- 2 h: 155 mg/dL (8.6 mmol/L)
- 3 h: 140 mg/dL (7.8 mmol/L)

^aAbbreviations: GDM, gestational diabetes mellitus; GLT, glucose load test; OGTT, oral glucose tolerance test.

^bFrom the ADA (2).

^cThe screening threshold is set by local consensus.

^dAmerican College of Obstetricians and Gynecologists notes that 1 elevated value can be used for diagnosis (250).

Recommendation: Either the 1-step or 2-step protocol may be used, depending on regional preferences. A (moderate)





糖尿病检验诊断报告模式专家共识

——世界华人检验与病理医师协会, 2018

附件 1. 糖尿病检验分项诊断报告模板

XXX 医院糖尿病检验分项诊断报告

姓名: XXX	样本号: XXXX	病区: XXXXXX	条码号: XXXXXXXXXXXX			
性别: X	病人编号: XXXX	标本种类: XXXX	送检医师: XXX			
年龄: XX 岁	科室: XXXXXX	临床诊断: 血糖异常				
序号	中文名称	项目简称	结果	参考区间	单位	检测方法
OGTT						己糖激酶法
1	空腹血糖	Glu	10.51↑	3.9-6.1	mmol/L	
2	0.5 小时血糖	Glu(0.5h)	13.55	-	mmol/L	
3	1 小时血糖	Glu(1h)	15.68	-	mmol/L	
4	2 小时血糖	Glu(2h)	16.73↑	<7.8	mmol/L	
糖化血红蛋白检测						高效液相色谱法
1	糖化血红蛋白	HbA1c	9.6↑	4-6	%	
检验诊断结论:						
1. 患者空腹血糖>7.0 mmol/L, 葡萄糖负荷后 2 小时血糖>11.1 mmol/L, 符合糖尿病时糖代谢异常状态, 请结合临床。						
2. 患者糖化血红蛋白>7%, 提示最近 2-3 月血糖控制不佳。						
医嘱时间: XXXX.XX.XX.XX		收样时间: XXXX.XX.XX.XX		检验时间: XXXX.XX.XX		
报告时间: XXXX.XX.XX.XX		检验者: XXX		审核者: XXX		地址: XXXXXXXX



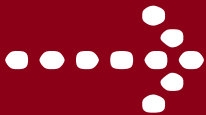


附件 2. 糖尿病检验综合诊断报告模板

XXX 医院糖尿病检验综合诊断报告（一）

姓名: xxx	样本号: xxxx	病区: xxxxxx	条码号: xxxxxxxxxxxx			
性别: x	病人编号: xxxxx	标本种类: xxxxx	送检医师: xxx			
年龄: xx 岁	科室: xxxxxx	临床诊断: 糖尿病				
序号	中文名称	项目简称	结果	参考区间	单位	检测方法
OGTT 己糖激酶法						
1	空腹血糖	Glu	17.89↑	3.9-6.1	mmol/L	
2	0.5 小时血糖	Glu(0.5h)	22.35	-	mmol/L	
3	1 小时血糖	Glu(1h)	24.28	-	mmol/L	
4	2 小时血糖	Glu(2h)	24.06↑	<7.8	mmol/L	
糖化血红蛋白检测 高效液相色谱法						
1	糖化血红蛋白	HbA1c	8.5↑	4-6	%	
胰岛 β 细胞功能检查 免疫发光法						
1	空腹胰岛素	INS	5.6	5.3-22.7	μIU/ml	
2	0.5 小时胰岛素	INS(0.5h)	10.5	-	μIU/ml	
3	1 小时胰岛素	INS (1h)	11.8	-	μIU/ml	
4	2 小时胰岛素	INS (2h)	12.1	-	μIU/ml	
5	空腹 C 肽	C-P	1.48	0.8-4.2	ng/ml	
6	0.5 小时 C 肽	C-P(0.5h)	2.05	-	ng/ml	
7	1 小时 C 肽	C-P(1h)	2.71	-	ng/ml	
8	2 小时 C 肽	C-P(2h)	3.01	-	ng/ml	
胰岛自身免疫抗体测定 酶联免疫吸附法						
1	谷氨酸脱羧酶抗体	GADA	阴性	阴性	-	
2	胰岛细胞抗体	ICA	阴性	阴性	-	
3	胰岛素自身抗体	IAA	阴性	阴性	-	
检验诊断结论:						
1. 患者空腹血糖>7.0 mmol/L，葡萄糖负荷后 2 小时血糖>11.1 mmol/L，符合糖尿病时糖代谢异常状态；						
2. 患者糖化血红蛋白>7%，提示最近 2-3 月血糖控制不佳；						
3. 患者胰岛 β 细胞功能检查示胰岛素、C 肽基础水平可，葡萄糖负荷后分泌高峰延迟、峰值较基础值升高幅度小；胰岛自身免疫抗体阴性，符合 2 型糖尿病特征，请结合临床。						





附件 3. 糖尿病检验综合诊断报告模板

XXX 医院糖尿病检验综合诊断报告（二）

姓名: XXX	样本号: XXXX	病区: XXXXXX	条码号: XXXXXXXXXXXXX			
性别: X	病人编号: XXXX	标本种类: XXXX	送检医师: XXX			
年龄: XX 岁	科室: XXXXXX	临床诊断: 糖尿病				
序号	中文名称	项目简称	结果	参考区间	单位	检测方法
OGTT			己糖激酶法			
1	空腹血糖	Glu	8.53↑	3.9-6.1	mmol/L	
2	0.5 小时血糖	Glu(0.5h)	9.61	-	mmol/L	
3	1 小时血糖	Glu(1h)	13.69	-	mmol/L	
4	2 小时血糖	Glu(2h)	16.21↑	<7.8	mmol/L	
糖化血红蛋白检测			高效液相色谱法			
1	糖化血红蛋白	HbA1c	8.2↑	4-6	%	
胰岛 β 细胞功能检查			免疫发光法			
1	空腹胰岛素	INS	5.40	5.3-22.7	μIU/ml	
2	0.5 小时胰岛素	INS(0.5h)	5.7	-	μIU/ml	
3	1 小时胰岛素	INS (1h)	6.3	-	μIU/ml	
4	2 小时胰岛素	INS (2h)	13.2	-	μIU/ml	
5	空腹 C 肽	C-P	1.30	0.8-4.2	ng/ml	
6	0.5 小时 C 肽	C-P(0.5h)	1.16	-	ng/ml	
7	1 小时 C 肽	C-P(1h)	1.33	-	ng/ml	
8	2 小时 C 肽	C-P(2h)	2.34	-	ng/ml	
自身免疫抗体测定			酶联免疫吸附法			
1	谷氨酸脱羧酶抗体	GADA	阴性	阴性	-	
2	胰岛细胞抗体	ICA	阴性	阴性	-	
3	人胰岛细胞抗原抗体	IAA	阴性	阴性	-	
血清肌酐检测			酶法			
1	肌酐	CRE	62	49-90	μmol/L	
尿常规检测（新鲜晨尿）			干化学法			
1	酮体	KET	-	阴性		
2	蛋白	PRO	+	阴性		

3	葡萄糖	Glu	3+	阴性
尿白蛋白检测（8 小时晨尿）				
免疫比浊法				
1	尿白蛋白	AlbU	93.0	<30 mg/L
检验诊断结论:				
1. 患者空腹血糖>7.0 mmol/L，葡萄糖负荷后 2 小时血糖>11.1 mmol/L，符合糖尿病时糖代谢异常状态。				
2. 患者糖化血红蛋白>7%，提示最近 2-3 月血糖控制不佳。				
3. 患者胰岛 β 细胞功能检查示胰岛素、C 肽基础水平可，葡萄糖负荷后分泌高峰延迟、峰值较基础值升高幅度小；胰岛自身免疫抗体阴性，符合 2 型糖尿病特征，请结合临床。				
4. 患者血清肌酐检测正常，计算 eGFR = 104ml/min/1.73m ² ，但尿蛋白阳性，计算尿白蛋白排泄率（UAE）为：193.8 ug/min，需除外糖尿病肾病可能，建议定期复查，请结合临床。				

医嘱时间: xxxx.xx.xx.xx 收样时间: xxxx.xx.xx.xx 检验时间: xxxx.xx.xx
报告时间: xxxx.xx.xx.xx 检验者: xxx 审核者: xxx 地址: xxxxxxxx





复习思考题

- 临床常用的糖代谢紊乱指标
- 如何用FPG与OGTT结果判断患者糖代谢紊乱的类型？

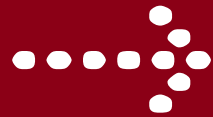




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@检验科张鹏医生

抖音号: changgong189

南方医科大学南方医院检验医学科副主任医师, 中...



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thanks