

ABIMO

ASSOCIAÇÃO BRASILEIRA DA INDÚSTRIA
DE DISPOSITIVOS MÉDICOS

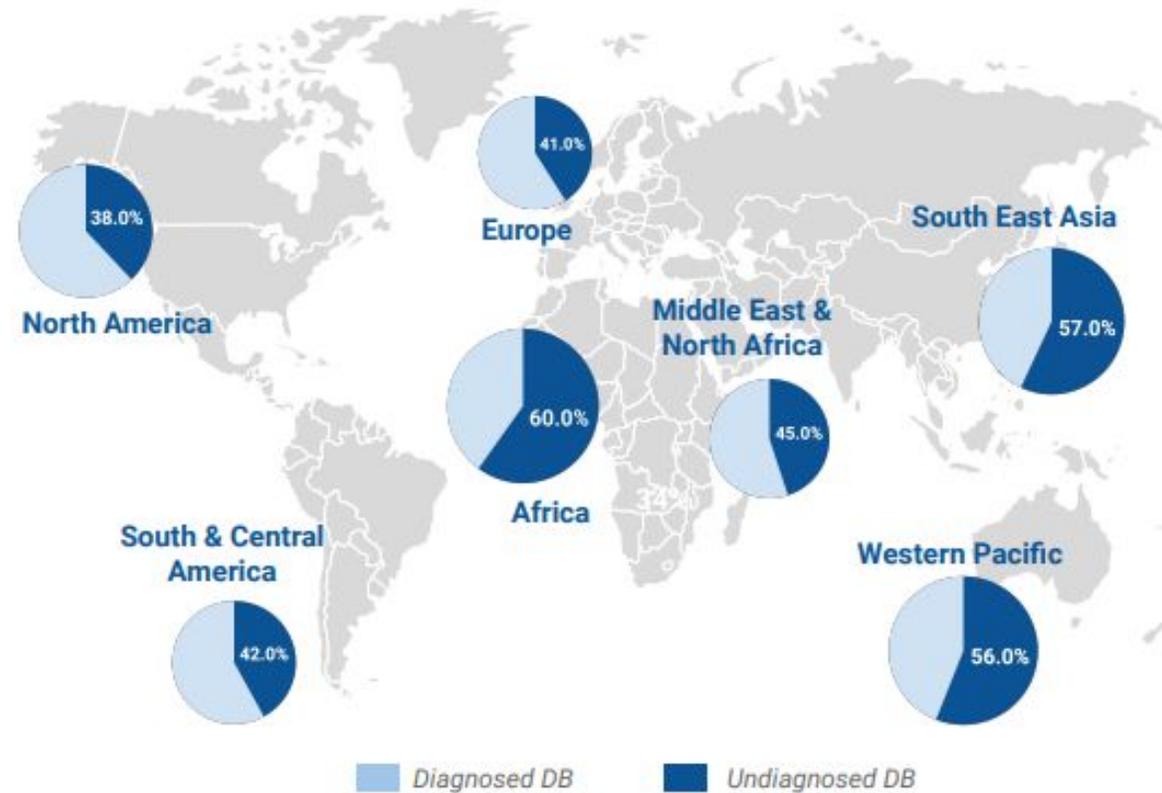
Acesso a ferramentas digitais de diagnóstico

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Por que acesso?

► Quality of Diabetes Diagnostics by World Region

Global Proportion of Undiagnosed Diabetes by Region, %



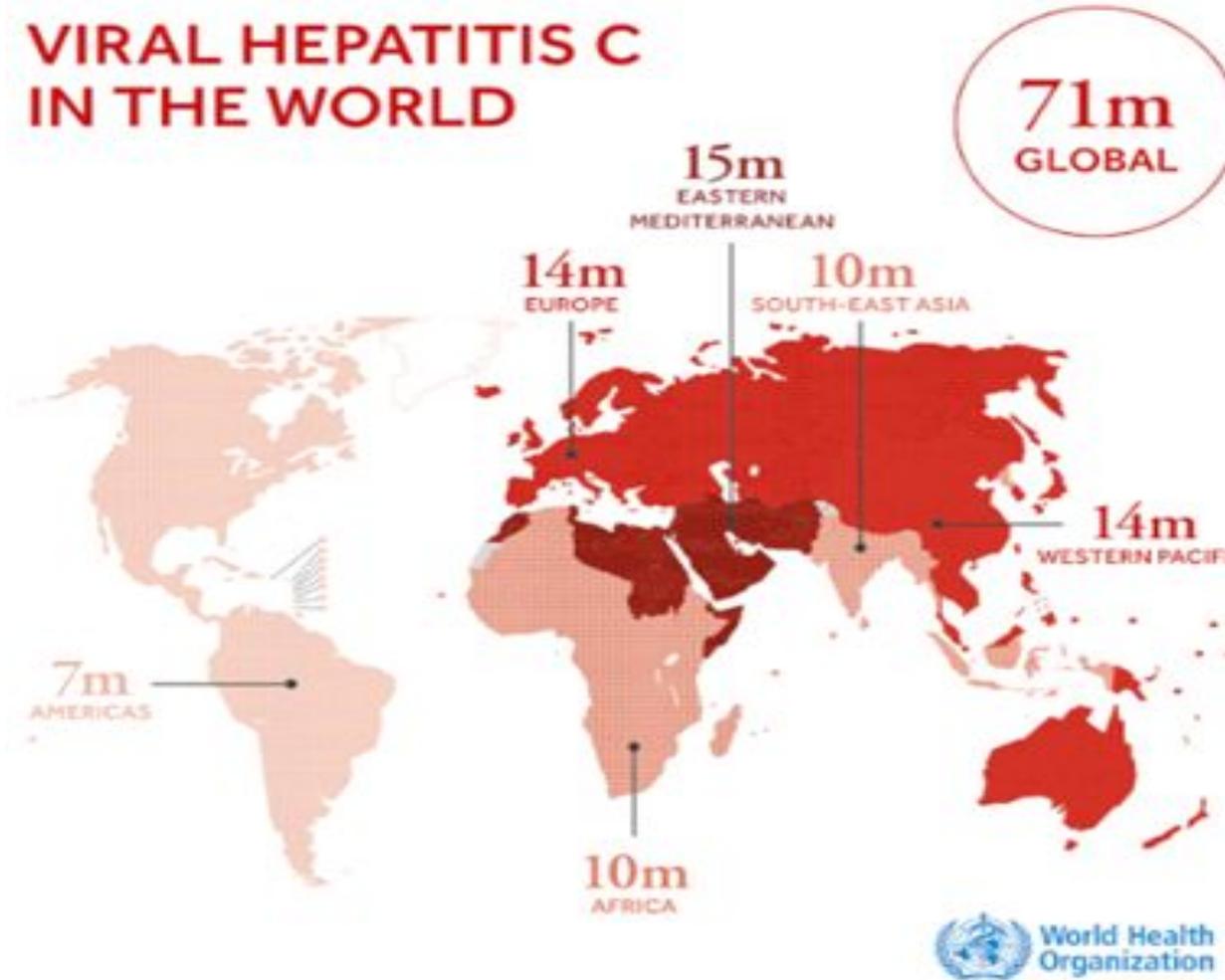
Aging Analytics Agency

Source: [International Diabetes Federation](#)

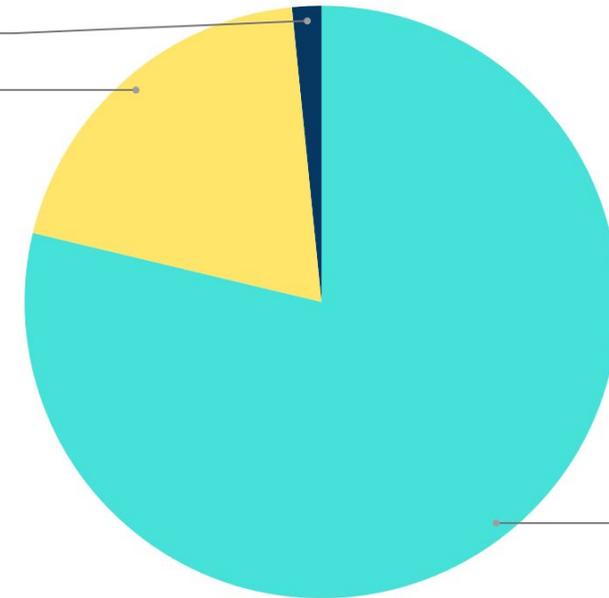
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Por que acesso?

VIRAL HEPATITIS C IN THE WORLD



Tratadas
1,6%
Diagnosticadas
19,7%

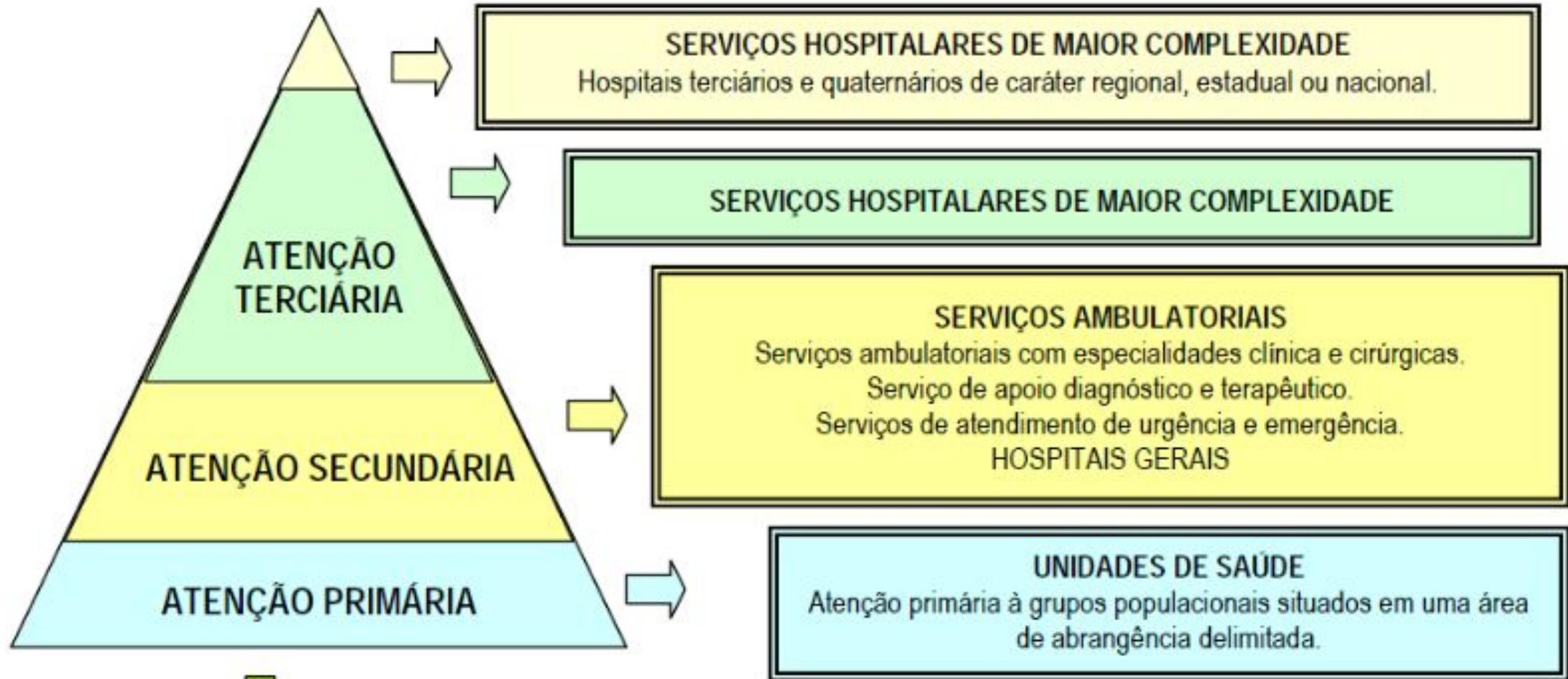


Não Diagnosticadas
78,7%

World Health Organization; Guidelines on Hepatitis B and C
Testing 2017

**QUAL É A SENSIBILIDADE DE UM EXAME
NÃO REALIZADO?**

Estrutura de Saúde



SUS



O SUS ainda enfrenta desafios

Relatório quadrimestral de indicadores

Painel Indicador

Dados sujeitos à alteração

Unidade Geográfica: Região

Indicador: Proporção de pessoas com diabetes, com consulta e hemoglobina glicada solicitada no semestre

Dados Preliminares:

Mostrar registros por página

Procurar:

Acompanhe a evolução dos indicadores:

■ < 20.0% ■ ≥ 20.0% e < 35 % ■ ≥ 35% e < 50% ■ ≥ 50%

Região	2022 Q1	2022 Q2	2022 Q3	2023 Q1	2023 Q2
CENTRO-OESTE	11 %	17 %	19 %	21 %	26 %
NORDESTE	16 %	24 %	27 %	29 %	33 %
NORTE	13 %	21 %	24 %	25 %	28 %
SUDESTE	11 %	16 %	18 %	21 %	24 %
SUL	14 %	21 %	24 %	25 %	31 %

O SUS ainda enfrenta desafios

Relatório quadrimestral de indicadores

Painel Indicador

Dados sujeitos à alteração

Unidade Geográfica: Região

Indicador: Proporção de mulheres com coleta de citopatológico na APS

Dados Preliminares:

Mostrar registros por página

Procurar:

Acompanhe a evolução dos indicadores:

■ < 16.0% ■ ≥ 16.0% e < 28 % ■ ≥ 28% e < 40% ■ ≥ 40%

Região	2022 Q1	2022 Q2	2022 Q3	2023 Q1	2023 Q2
CENTRO-OESTE	14 %	15 %	17 %	19 %	22 %
NORDESTE	17 %	20 %	22 %	25 %	28 %
NORTE	15 %	17 %	19 %	22 %	25 %
SUDESTE	16 %	17 %	19 %	21 %	24 %
SUL	20 %	21 %	24 %	26 %	29 %

O SUS ainda enfrenta desafios

Relatório quadrimestral de indicadores

Painel Indicador

Dados sujeitos à alteração

Unidade Geográfica: Região

Indicador: Proporção de gestantes com realização de exames para sífilis e HIV

Dados Preliminares:

Mostrar registros por página

Procurar:

Acompanhe a evolução dos indicadores:

■ < 24.0% ■ ≥ 24.0% e < 42 % ■ ≥ 42% e < 60% ■ ≥ 60%

Região	2022 Q1	2022 Q2	2022 Q3	2023 Q1	2023 Q2
CENTRO-OESTE	57 %	64 %	65 %	71 %	73 %
NORDESTE	64 %	69 %	70 %	75 %	79 %
NORTE	65 %	68 %	72 %	75 %	76 %
SUDESTE	47 %	51 %	51 %	60 %	65 %
SUL	60 %	67 %	64 %	72 %	78 %

Exibindo de 1 a 5 de 5 registros

Anterior **1** Próximo

O SUS ainda enfrenta desafios

Relatório quadrimestral de indicadores

Painel Indicador

Dados sujeitos à alteração

Unidade Geográfica: Região

Indicador: Proporção de pessoas com hipertensão, com consulta e pressão arterial aferida no semestre

Dados Preliminares:

Mostrar registros por página

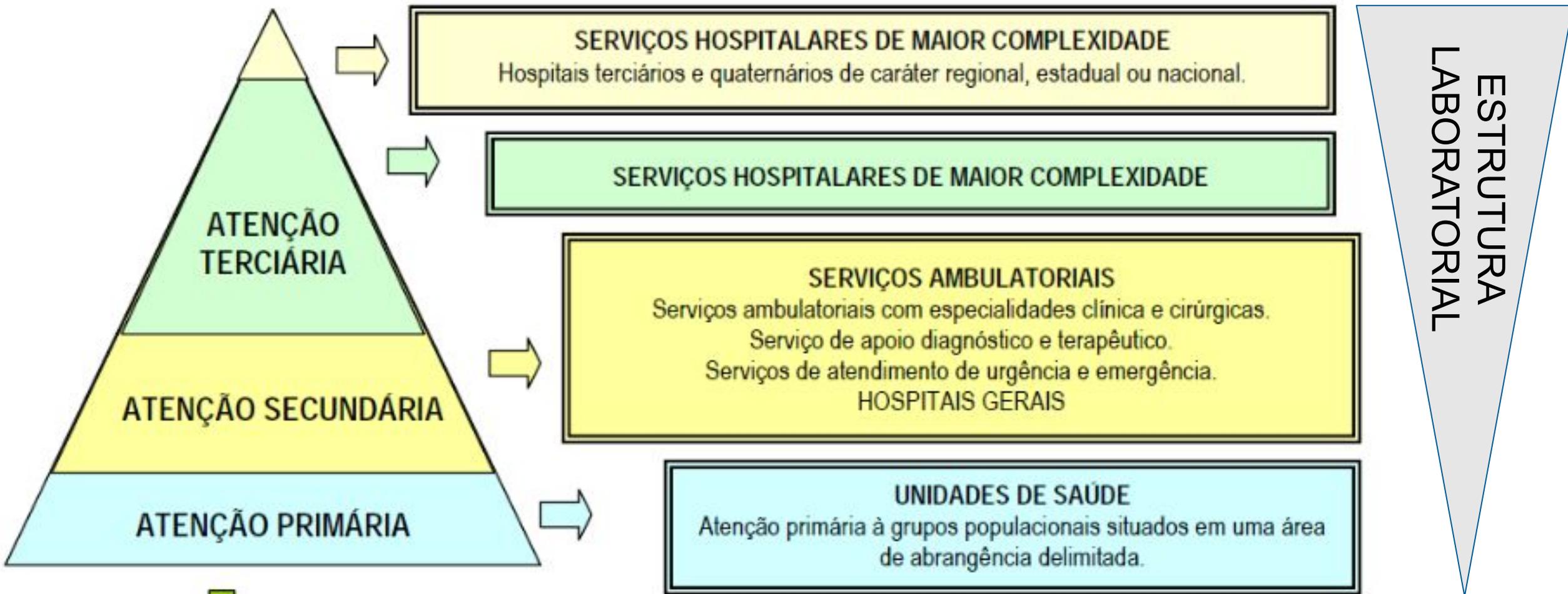
Procurar:

Acompanhe a evolução dos indicadores:

■ < 20.0% ■ ≥ 20.0% e < 35% ■ ≥ 35% e < 50% ■ ≥ 50%

Região	2022 Q1	2022 Q2	2022 Q3	2023 Q1	2023 Q2
CENTRO-OESTE	17 %	23 %	24 %	26 %	30 %
NORDESTE	21 %	28 %	30 %	31 %	35 %
NORTE	19 %	24 %	26 %	28 %	31 %
SUDESTE	16 %	21 %	24 %	25 %	29 %
SUL	18 %	24 %	28 %	29 %	33 %

A rede laboratorial está desconectada à estrutura de saúde



A rede laboratorial está desconectada à estrutura de saúde

DESCENTRALIZAÇÃO + INTEROPERABILIDADE

TELESSAÚDE / TELEMEDICINA / SAÚDE DIGITAL

MONITORAMENTO E AVALIAÇÃO

Cases bem sucedidos - HIV

18

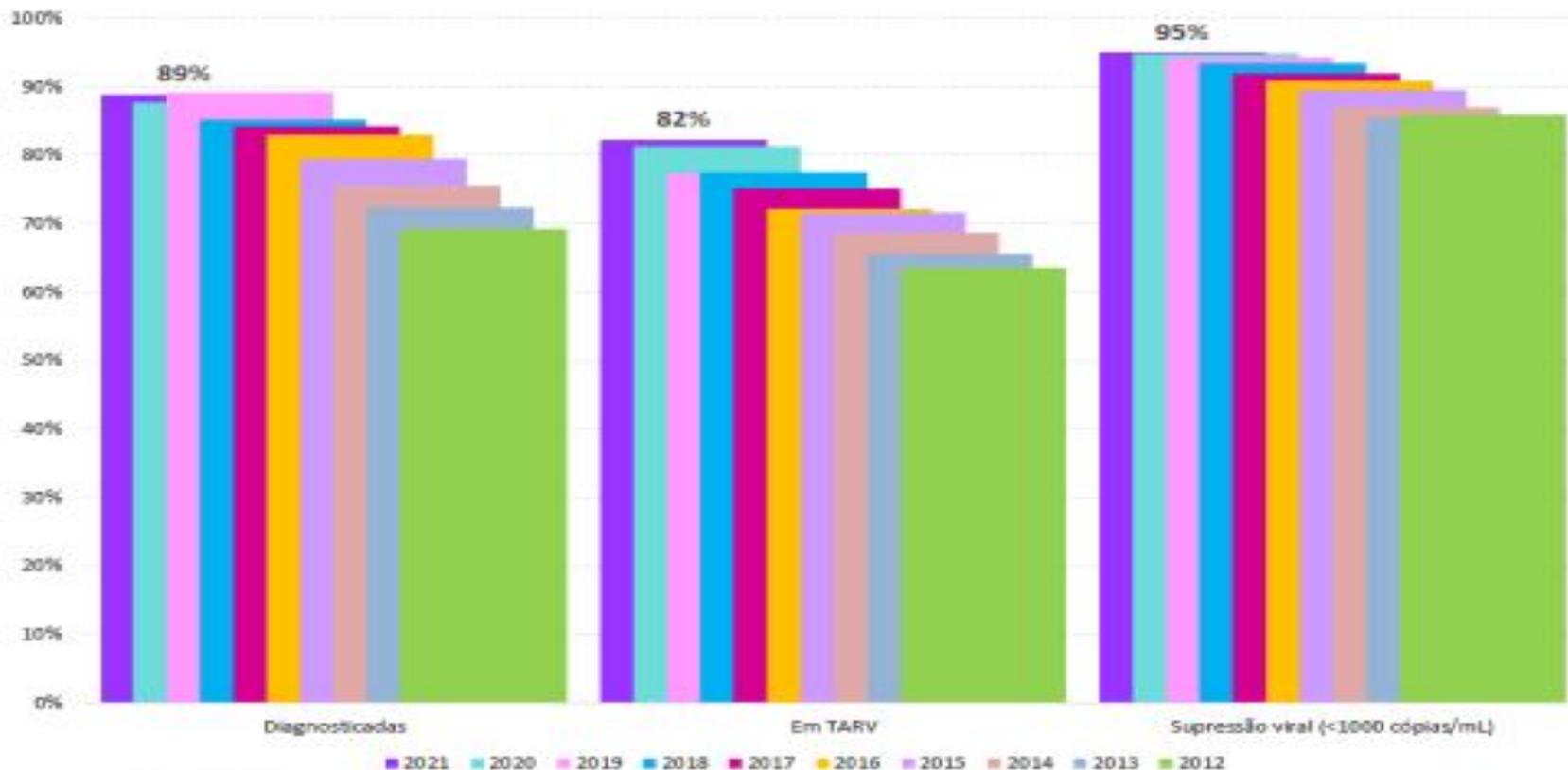


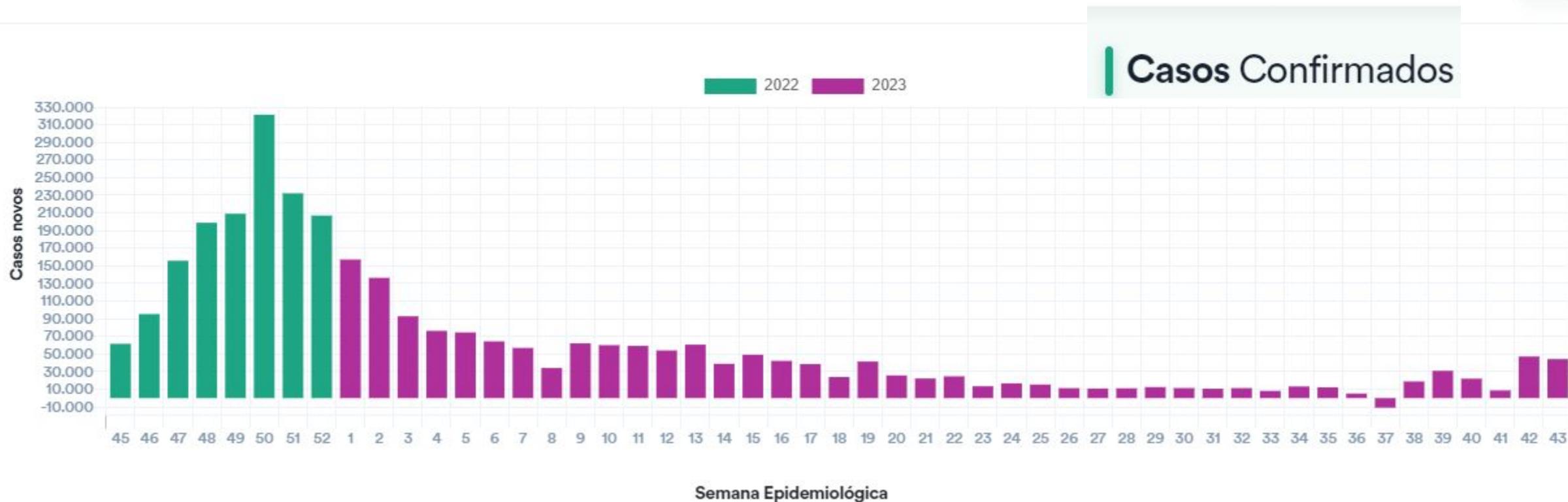
Figura 4. Status do alcance das metas 95-95-95. Brasil, 2012-2021

Fonte: DCCI/SVS/MS.

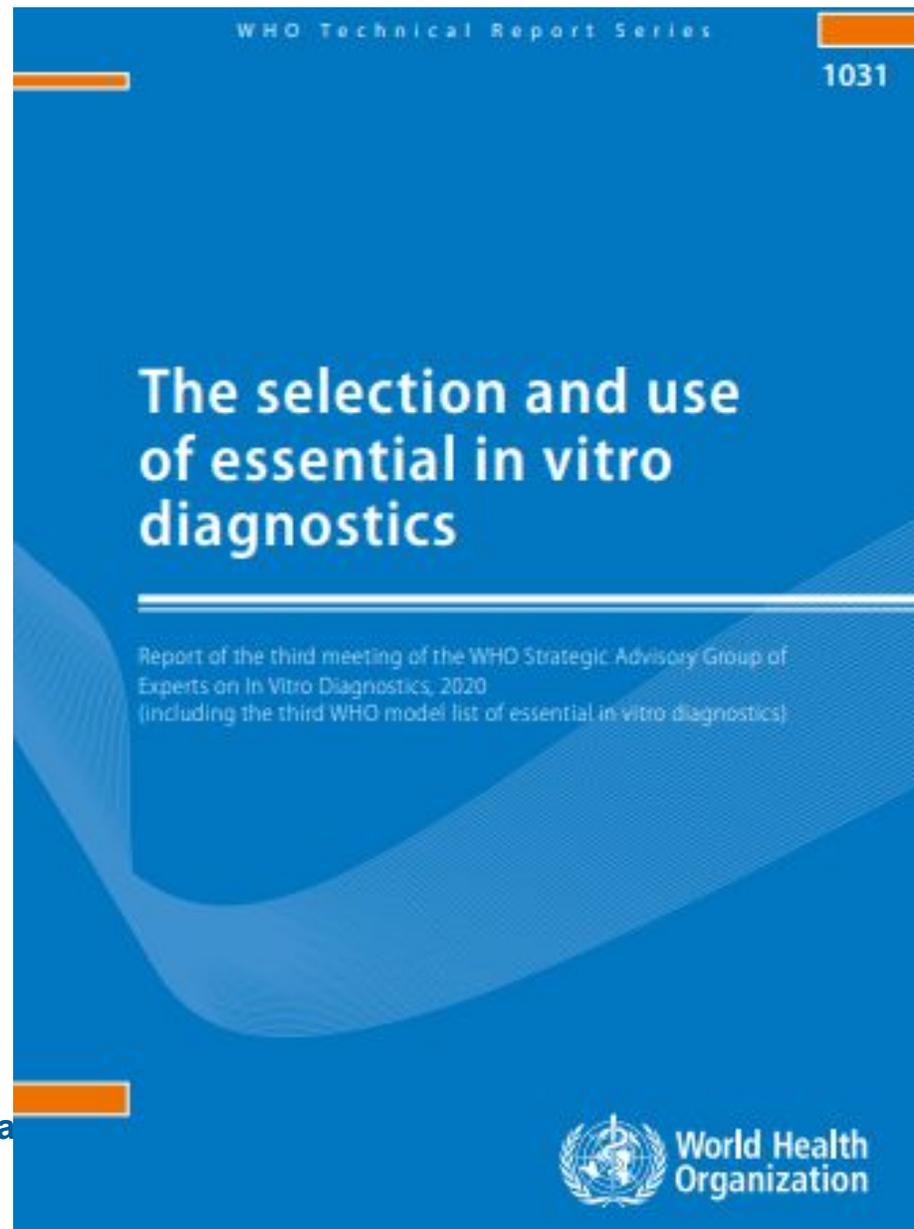
Cases bem sucedidos - COVID-19

Casos novos de COVID-19 por Semana Epidemiológica de notificação

CORONAVÍRUS // BRASIL



Recomendações OMS



Recomendações OMS

I.b Disease-specific IVDs for use in community settings and health facilities without laboratories *continued*

Disease	Diagnostic test	Test purpose	Assay format	Specimen type	WHO prequalified or recommended products	WHO supporting documents
Diabetes mellitus <i>continued</i>	Haemoglobin A1c (HbA1c)	To diagnose and monitor diabetes mellitus	Handheld and small analysers	Capillary whole blood	N/A	HEARTS-D: diagnosis and management of type 2 diabetes (2020) https://www.who.int/publications/i/item/who-ucn-ncd-20.1 https://www.who.int/health-topics/diabetes#tab=tab_1
Hepatitis B virus (HBV) infection	Hepatitis B surface antigen (HBsAg)	To screen for HBV infection, or to aid in the diagnosis of chronic and acute HBV infection: infants > 12 months of age, children, adolescents and adults	RDT	Capillary whole blood Venous whole blood ¹⁰	Public reports of WHO-prequalified IVDs https://extranet.who.int/pqweb/vitro-diagnostics/prequalification-reports/whopr?field_whopr_category=63	Guidelines on hepatitis B and C testing (February 2017) https://apps.who.int/iris/handle/10665/254621 https://www.who.int/news-room/fact-sheets/detail/hepatitis-b

Recomendações OMS

I.b Disease-specific IVDs for use in community settings and health facilities without laboratories *continued*

Disease	Diagnostic test	Test purpose	Assay format	Specimen type	WHO prequalified or recommended products	WHO supporting documents
Hepatitis B virus (HBV) infection <i>continued</i>	Hepatitis B e antigen (HBeAg)	Staging to assess the need for HBV treatment in chronic HBV infection and as a criterion for use of antivirals in the mother to prevent mother-to-child transmission (if HBV DNA test is not available) (Only for use where an HBV DNA test is not available)	RDT	Capillary whole blood Venous whole blood ¹¹	N/A	
Hepatitis C virus (HCV) infection	Antibodies to hepatitis C virus (HCV) (anti-HCV)	To screen for or to aid in the diagnosis of viraemic HCV infection: infants > 18 months of age, children, adolescents and adults	RDT	Oral fluid Capillary whole blood Venous whole blood ¹¹	Public reports of WHO prequalified IVDs https://extranet.who.int/pqweb/vitro-diagnostics/prequalification-reports/whopr?field_whopr_category=59	Guidelines on hepatitis B and C testing (February 2017) https://apps.who.int/iris/handle/10665/254621 https://www.who.int/news-room/fact-sheets/detail/hepatitis-c

Recomendações OMS

I.b Disease-specific IVDs for use in community settings and health facilities without laboratories <i>continued</i>						
Disease	Diagnostic test	Test purpose	Assay format	Specimen type	WHO prequalified or recommended products	WHO supporting documents
Influenza	Influenza A and B antigen	To aid in the diagnosis of seasonal influenza infection (Not recommended for surveillance testing)	RDT <hr/> Instrument-based point-of-care immunoassay	Nasal swab Nasopharyngeal swab Nasopharyngeal aspirate or wash	N/A	Use of influenza rapid diagnostic tests (2010) https://apps.who.int/iris/handle/10665/44304/ Manual for the laboratory diagnosis and virological surveillance of influenza (2011) https://apps.who.int/iris/handle/10665/44518
	Influenza A and B nucleic acid test	To diagnose seasonal influenza infection	Point-of-care NAT	Nasal swab Nasopharyngeal swab Nasopharyngeal aspirate or wash	N/A	Global Epidemiological Surveillance Standards for Influenza (2014) https://www.who.int/influenza/resources/documents/WHO_Epidemiological_Influenza_Surveillance_Standards_2014.pdf https://www.who.int/health-topics/influenza-seasonal#tab=tab_1

Recomendações OMS

I.b Disease-specific IVDs for use in community settings and health facilities without laboratories <i>continued</i>						
Disease	Diagnostic test	Test purpose	Assay format	Specimen type	WHO prequalified or recommended products	WHO supporting documents
Malaria	<i>Plasmodium</i> spp. antigens; species-specific (e.g. HRP2) and/or pan-species specific (e.g. pan-pLDH)	To diagnose one or more human malaria parasite species (<i>P. falciparum</i> , <i>P. vivax</i> , <i>P. malariae</i> , <i>P. ovale</i>)	RDT	Capillary whole blood Venous whole blood ¹⁵	Public reports of WHO prequalified IVDs https://extranet.who.int/pqweb/vitro-diagnostics/prequalification-reports/whopr?field_whopr_category=64	<p>WHO guidelines for the treatment of malaria, third edition (2015) https://apps.who.int/iris/handle/10665/162441</p> <p>Malaria rapid diagnostic test performance: results of WHO product testing of malaria RDTs: round 8 (2016–2018) https://apps.who.int/iris/handle/10665/276190</p> <p>WHO good practices for selecting and procuring rapid diagnostic tests for malaria (2011) https://apps.who.int/iris/handle/10665/44530</p> <p>Information note on recommended selection criteria for procurement of malaria rapid diagnostic tests https://apps.who.int/iris/handle/10665/259870</p> <p>https://www.who.int/health-topics/malaria#tab=tab_1</p>

Recomendações OMS

I.b Disease-specific IVDs for use in community settings and health facilities without laboratories <i>continued</i>						
Disease	Diagnostic test	Test purpose	Assay format	Specimen type	WHO prequalified or recommended products	WHO supporting documents
Streptococcal pharyngitis	Group A <i>Streptococcus</i> antigen	To aid in the diagnosis of Group A streptococcal pharyngitis	RDT	Throat swab	N/A	N/A
Sickling disorders	Sickle cell testing	To screen for or to aid in the diagnosis of sickle cell disease, C trait (SCT) and other variant sickling disorders	RDT	Capillary whole blood Venous whole blood ¹⁶	N/A	N/A
Syphilis	Antibodies to <i>Treponema pallidum</i>	To diagnose or to aid in the diagnosis of <i>T. pallidum</i>	RDT	Capillary whole blood Venous whole blood ¹⁶	N/A	WHO laboratory diagnosis of sexually transmitted infections, including human immunodeficiency virus (2013) https://apps.who.int/iris/handle/10665/85343 https://www.who.int/news-room/fact-sheets/detail/sexually-transmitted-infections-stis
	Combined antibodies to <i>T. pallidum</i> and HIV-1/2	To diagnose or to aid in the diagnosis of HIV-1/2 and/or <i>T. pallidum</i>	RDT	Capillary whole blood Venous whole blood ¹⁶	Public reports of WHO prequalified IVDs https://extranet.who.int/pqweb/vitro-diagnostics/prequalification-reports/whopr?field_whopr_category=57	Consolidated guidelines on HIV testing services (December 2019) https://www.who.int/publications/i/item/978-92-4-155058-1

Recomendações OMS

II.a General IVDs for use in clinical laboratories <i>continued</i>				
Discipline	Diagnostic test	Test purpose	Assay format	Specimen type
Clinical chemistry <i>continued</i>	Total calcium	To identify hypercalcaemia or hypocalcaemia, to assess calcium metabolism, to monitor total calcium levels in patients with underlying disease such as certain kinds of cancer (e.g. multiple myeloma, breast cancer and lung cancer), kidney disease, parathyroid disorder or malabsorption.	Semi-automated or automated chemistry analyser	Serum Plasma
	Ionized calcium	To measure free (ionized) calcium in situations in which there are changes in the concentrations of certain proteins (such as albumin) and/or changes in physiological status such as acid–base disorders. To diagnose and monitor hypercalcemia or hypocalcaemia.	Blood gas analysers, including portable analysers for emergency and critical care	Arterial whole blood Venous whole blood Capillary whole blood
	Creatinine	To assess kidney function through estimated glomerular filtration rate (eGFR), urine albumin : creatinine ratio (ACR) and urine protein : creatinine ratio. <i>Note: When used for emergency or critical care, results are time-sensitive.</i>	Electrochemical or optical methods on semi-automated or automated chemistry analysers	Serum Urine
	Electrolytes (sodium, potassium, chloride and bicarbonate ²⁷)	To monitor fluid, electrolyte and acid–base balance <i>Note: When used for emergency or critical care, results are time-sensitive.</i>	Electrochemical or optical methods on semi-automated or automated chemistry analyser	Serum Plasma

Recomendações OMS

II.a General IVDs for use in clinical laboratories <i>continued</i>				
Discipline	Diagnostic test	Test purpose	Assay format	Specimen type
Clinical chemistry <i>continued</i>	Glucose	To diagnose hypoglycaemia <i>Note: When used for emergency or critical care, results are time-sensitive.</i>	Optical and electrochemical methods on semi-automated or automated chemistry analysers and handheld analyzers.	Serum Plasma Capillary whole blood
	Glucose-6-phosphate dehydrogenase (G6PD)	<ul style="list-style-type: none"> To screen newborns for G6PD deficiency To determine G6PD activity (normal, intermediate, deficient) for a decision to administer oxidant drugs, e.g. 8-aminoquinoline drugs for radical cure of <i>P. vivax</i> malaria²⁸ 	Semi-quantitative fluorescent spot test	Venous whole blood
	Lipase or amylase	To assess acute pancreatitis and other pancreatic disorders <i>Note: Lipase result is time-sensitive for emergency and critical care.</i>	Optical methods, automated chemistry analyser if available	Serum Plasma Peritoneal fluid (amylase)
	Lipid profile	To assess risk of cardiovascular disease (CVD) by measuring cholesterol, triglycerides, high-density lipoprotein (HDL) and low-density lipoprotein (LDL) ²⁹	Optical methods, automated chemistry analyser if available	Plasma Serum
	Procalcitonin	To guide antibiotic therapy or its discontinuation in sepsis and lower respiratory tract infections (For use only in tertiary care facilities and above)	RDT Point-of-care immunoassay Immunoassay	Serum Plasma Venous whole blood Capillary whole blood Plasma Serum Plasma

O que se espera?

1. Ampliação dos serviços baseados em Telessaúde e Telemedicina à rede assistencial
2. Avaliação de novas tecnologias e critérios de especificações baseados em desfechos clínicos, incorporando aspectos analíticos à outros indicadores como prevalência / subdiagnóstico / efetividade das linhas de cuidado
3. Descentralização do serviço laboratorial como Política Pública, considerando os testes essenciais à Atenção Primária (OMS);
4. Incorporação de Indicadores laboratoriais como forma de vigilância e monitoramento das principais doenças na Atenção Primária.

Barreiras à incorporação no SUS

16. RECOMENDAÇÃO FINAL DA CONITEC

Pelo exposto, o Comitê de Produtos e Procedimentos, na 119ª Reunião Ordinária da Conitec, no dia 1º de junho de 2023, deliberou, por unanimidade, recomendar a não incorporação do *point-of-care testing* de hemoglobina glicada para pacientes diabéticos no SUS. Os membros do Comitê de Produtos e Procedimentos consideraram que a implementação do *point-of-care* de hemoglobina glicada estaria relacionada a barreiras importantes devido à grande escala prevista para atendimento e às incertezas de que a utilização desse produto no contexto do SUS estaria relacionada à melhoria em desfechos clínicos importantes para a doença. Por fim, foi assinado o Registro de Deliberação nº 831/2023.

Especificações para análise devem ser aderentes às necessidades do sistema e baseado em desfechos clínicos

- subdiagnóstico / controle de doenças / custo-efetividade / M&A

Ex: HIV (Ac/Ag x CV) / COVID-19 (Ag x PCR)

ABIMO

APOIO, DESENVOLVIMENTO E INOVAÇÃO



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