



PROVIDER GUIDE

Hemoglobin A1C

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ABOUT LETSGETCHECKED

[Client name] has partnered with LetsGetChecked to make it easier for patients to complete recommended screenings. LetsGetChecked is a global healthcare solutions company that helps providers connect patients to better health through testing, accessible health insights, virtual consultations, and medication delivery for a wide range of health and wellness conditions. LetsGetChecked’s comprehensive at-home healthcare solutions integrate seamlessly into care offerings to help improve the patient experience and health outcomes.

OVERVIEW

LetsGetChecked makes it easy for providers, health plans, and other organizations to orchestrate hemoglobin A1C testing programs at scale to help people who have diabetes - but are not engaged in the healthcare system - monitor their condition. The test helps providers and plans identify patients who are likely to become high-cost utilizers if not placed into a regular pattern of care.

HOW LETSGETCHECKED’S HEMOGLOBIN A1C SCREENING WORKS

Patients have a seamless experience as they receive their test, collect their sample, and receive their results – all without leaving their home. Results will be shared with patients and providers to ensure proper follow up care and treatment.



Step 1
Health Plan & LGC identify specific patients eligible for hemoglobin A1C testing.



Step 2
LGC delivers sample collection kits from our ISO 13485 accredited facility to the patient’s home.



Step 3
The patient collects the sample and sends it to the lab in the prepaid shipping envelope.



Step 4
Our CLIA approved and CAP-accredited lab processes the sample.



Step 5
Both the patient and their PCP receive results online and/or by mail.

WHAT IS IN THE KIT?



HOW DOES MY PATIENT COMPLETE THE TEST?

The patient receives a sample collection test kit with easy-to-follow instructions. The patient provides a blood sample from the privacy of their home and sends it to the LetsGetChecked lab.

HOW DOES LETSGETCHECKED OVERSEE THE ADMINISTRATION OF THIS TEST?

Our laboratories are CLIA approved and CAP-accredited, which are the highest levels of accreditation. In addition, our labs complete validation studies to ensure accuracy of the test.

Sample collection kits are manufactured within our ISO 13485 accredited facility, the highest level of accreditation for medical devices.

HOW DO MY PATIENT AND I RECEIVE RESULTS?

ABNORMAL RESULT NOTIFICATION

When a lab processes the test and the result is abnormal, the LetsGetChecked clinical staff will reach out to the patient immediately. In addition, the patient and their primary care provider will receive mailed letters with results. The patient may reach out to you for further guidance and recommendations.

NORMAL RESULT NOTIFICATIONS

Patients and their providers receive mailed result letters. Please see [Attachment 1](#) – Sample Results Letters.

NOTIFICATIONS FOR TESTING NOT PERFORMED

There are instances where the laboratory was unable to run the test. Patients are notified and another test kit is mailed. Patients may call you to inquire about why testing was not performed. Please refer them to LetsGetChecked.

HOW LONG DOES THE ENTIRE TESTING PROCESS TAKE?

Results are typically processed within a few days and then will be sent to the patient and provider via mail.

WHY AT-HOME HEMOGLOBIN A1C SCREENING?

Patients in [health plan] program who have been identified with a gap in care for hemoglobin A1C will receive an at-home sample collection kit from LetsGetChecked.

We hope that by increasing the convenience of this test and addressing barriers like time and transportation, we are providing one more way for patients to get the care they need, when they need it. We encourage you to discuss this test with your patient if they ask.

WHAT IS LETSGETCHECKED’S CLINICAL DATA FOR A1C?

VERIFICATION OF HEMOGLOBIN A1C IN WHOLE BLOOD ON THE ROCHE COBAS C513 ANALYZER

Accuracy

STUDY DESIGN

HbA1c% accuracy was challenged using certified reference materials (N=32) purchased for proficiency testing (GH5 and Calibration Verification/Linearity) from the CAP.

VERIFICATION CRITERIA

HbA1c% results measured by the Roche Cobas c513 and c502 were compared to the CAP defined Reference Method Target, c513 mean, and c500 Series mean acceptable ranges. Accuracy passes if measured HbA1c% values fall within the CAP defined acceptable range.

RESULTS

SUMMARY OF ACCURACY

Instrument	Average Bias	Pass/Fail
Roche cobas c513	1.59%	PASS

Precision

STUDY DESIGN

BioRad Liquichek Diabetes Control Levels 1 (Low), 2 (Mid), and 3 (High) were utilized in the intraday and between-day precision studies for HbA1c%. These levels span the calibration range of the HbA1c assay on the Roche Cobas c513 analyzer. Target values utilized in the study were obtained from peer group data.

Intraday Precision: HbA1c%

Each level was processed and run over the course of one (1) business day. Twenty (20) consecutive replicates were assayed at each level. Statistics were calculated for intraday precision using EP Evaluator’s Simple Precision Module.

Between-Day Precision: HbA1c%

Each level was processed and run over the course of five (5) business days. Five (5) replicates were assayed at each level each day. Statistics were calculated for between-day precision using EP Evaluator’s Complex Precision Module.

VERIFICATION CRITERIA

The total imprecision contribution is considered in the TEa requirement as the random error component. EP Evaluator calculates the absolute SD and if it does not exceed the verification value which is the largest SD that is not significantly different, the experiment would pass precision.

In addition, the mean achieved from each study should be less than two SD from the peer group mean and the SD achieved from each study should be less than that of the peer group.

RESULTS

Summary of Intraday Precision

BioRad Liquichek Diabetes Control	Level 1	Level 2	Level 3
HbA1c Peer Group Mean (%)	5.42	8.86	12.27
Observed Mean (%)	5.4	8.8	11.8
Observed SD (%)	0.02	0.07	0.24
Observed CV (%)	0.4	0.8	2.0
Pass/Fail	PASS	PASS	PASS

SUMMARY OF BETWEEN-DAY PRECISION

BioRad Liquichek Diabetes Control	Level 1	Level 2	Level 3
HbA1c Peer Group Mean (%)	5.42	8.86	12.27
Observed Mean (%)	5.5	8.8	12.0
Observed SD (%)	0.05	0.09	0.21
Intraday CV (%)	0.8	0.8	0.6
Between-Day CV (%)	0.9	1.0	1.8
Total %CV	1.2	1.3	1.8

Level 1 (Low): Intraday and between-day %CVs were calculated to be 0.8% and 0.9%, respectively. Total %CV was calculated to be 1.2%. Because intraday, between-day, and Total %CVs were less than the maximum allowable %CV of $\pm 6.0\%$, the precision study **passed** for HbA1c at a Low concentration (5.42%). The observed mean of 5.5% is less than two SD from the peer group mean (5.42%) and the observed SD of 0.05% is less than the peer group SD (0.093%).

Level 2 (Mid): Intraday and between-day %CVs were calculated to be 0.8% and 1.0%, respectively. Total %CV was calculated to be 1.3%. Because intraday, between-day, and Total %CVs were less than the maximum allowable %CV of $\pm 6.0\%$, the precision study **passed** for HbA1c at a Mid concentration (8.86%). The observed mean of 8.8% is within two SD of the peer group mean (8.86%) and the observed SD of 0.09 is less than the peer group SD (0.167).

Level 3 (High): Intraday and between-day %CVs were calculated to be 0.6% and 1.8%, respectively. Total %CV was calculated to be 1.8%. Because intraday, between-day, and Total %CVs were less than the maximum allowable %CV of $\pm 6.0\%$, the precision study **passed** for HbA1c at a High concentration (12.27%). The observed mean of 12.0% is within two SD of the peer group mean (12.27%) and the observed SD of 0.21 is less than the peer group SD (0.300).

Correlation

STUDY DESIGN

The method comparison study was carried out utilizing the procedure in CLSI Guideline EP09-A3: Measurement Procedure Comparison and Bias Estimation Using certified reference material. The regression analysis was performed using the EP Evaluator Alternate (Quantitative) Method Comparison module.

Fifty-nine (59) venous whole blood specimens were tested using the HbA1c assay on the Roche Cobas c502 Asclepius analyzer. These samples were tested, and results were compared with those from the Roche Cobas c513 analyzer.

VERIFICATION CRITERIA

The Method Comparison study passes if the slope of the data is between 0.85 – 1.15, with a Deming Correlation Coefficient (R) greater than or equal to 0.90, and an average absolute bias less than or equal to the Total Allowable Error of 6.0% at the medical decision point of 6.5%.

RESULTS

Summary of Correlation

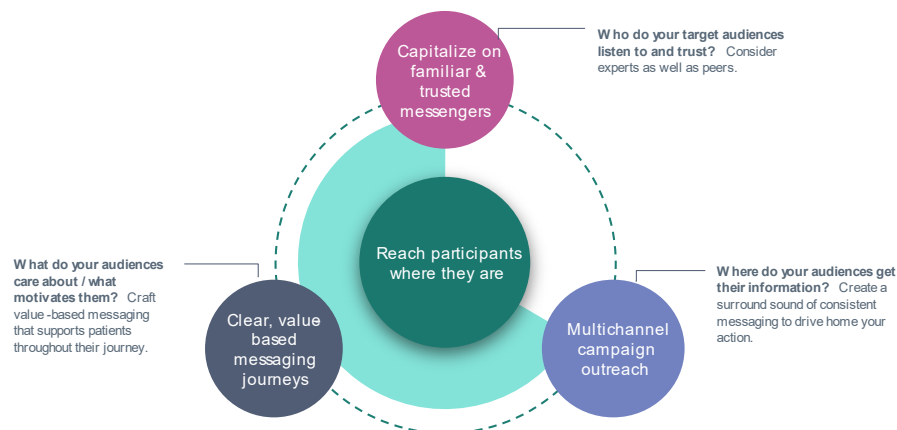
Analyte	Slope	y-intercept	R (Deming)	Avg Bias (%)	MDP Bias (%)	Pass/Fail
HbA1c (%)	0.917	0.74	0.9909	5.64	3.08	PASS

HOW CAN I ENCOURAGE MY PATIENTS TO PARTICIPATE IN A1C TESTING?

You could discuss the benefits of hemoglobin A1C screening with your eligible patients during a regular office visit or with a regularly scheduled phone call. Your office staff could also discuss the benefits of at-home testing. Please see [Attachment 2](#) for more information.

In addition, LetsGetChecked will assist you in sharing this important message. We use a multichannel approach to reach participants. See [Attachment 3](#) for sample communications.

Meets patients where they are in their well-being journey



CONTACT US

 <https://www.letsgetchecked.com/contact-us/>

 1-800-984-9837

ATTACHMENTS

- [Attachment 1](#) – Sample Results Letters
- [Attachment 2](#) – Sample Provider-Patient Talking Points
- [Attachment 3](#) – Sample Communications

REFERENCES


¹Centers for Disease Control and Prevention. National Diabetes Statistics Report. (2022, June 29). CDC.

[https://www.cdc.gov/diabetes/data/statistics-](https://www.cdc.gov/diabetes/data/statistics-report/index.html?ACSTrackingID=DM72996&ACSTrackingLabel=New%20Report%20Shares%20Latest%20Diabetes%20Stats%20&deliveryName=DM72996#print)

[report/index.html?ACSTrackingID=DM72996&ACSTrackingLabel=New%20Report%20Shares%20Latest%20Diabetes%20Stats%20&deliveryName=DM72996#print](https://www.cdc.gov/diabetes/data/statistics-report/index.html?ACSTrackingID=DM72996&ACSTrackingLabel=New%20Report%20Shares%20Latest%20Diabetes%20Stats%20&deliveryName=DM72996#print)

Attachment 1 – Sample Result Letters

Patient



<Member First Name> <Member Last Name>
 <Address Line 1>
 <Address Line 2>
 <City>, <State> <Zip Code>

<Date>


Dear <Member First Name> <Member Last Name>,

Thank you for choosing to take the LetsGetChecked at-home health test provided by your health plan. We have processed your sample, and these are your test results.

Your HbA1c test result has been returned as <A1c Result>% on <Result Date>.

This test is important because it helps you and your health care provider monitor your blood sugar levels over the past two to three months. When you have a diagnosis of diabetes, your target blood sugar level will depend on many things, such as your age and other medical conditions.

We encourage you to contact your provider to discuss these results. A common target level for people with diabetes is 7% or less, however, your provider can advise what target level is best for you. Remember, HbA1c testing doesn't replace regular blood sugar testing at home.




Please share these results with your primary care physician. If you have any questions about your test, please call LetsGetChecked at <1-XXX-XXX-XXXX> 8am – 8pm ET, Monday to Friday, and we can discuss this result with you and provide advice on your next steps.

We are here to help and support you.

Sincerely,

Robert Mordkin, MD
 Chief Medical Officer



Provider



<Provider First Name> <Provider Last Name>
 <Provider Address 1>
 <Provider Address 2>
 <Provider City>, < State> <Zip Code>

Re: <Member First Name> <Member Last Name>
 <Member Address 1>
 <Member Address 2>
 <Member City>, <State> <Zip Code>

<Date>

Dear Dr. <Provider Last Name>,

Your patient, <Member First Name> <Last Name>, (DOB: <Member DOB>), recently took a LetsGetChecked at-home screening test provided by their health plan. Below are the results:

HbA1c result has been returned as <Result Value> % on <Result Date>.

The patient has been sent these results. Please follow up with your patient to discuss these results and any follow-up testing or treatment needed. If you have any questions, please call LetsGetChecked at 1 <XXX-XXX-XXXX> 8am - 8pm ET, Monday to Friday.

Sincerely,

Robert Mordkin, MD
 Chief Medical Officer




Attachment 2 – Sample Provider-Patient Talking Points



- Sample collection is easy and can be done in the privacy, safety, and comfort of your own home.
- There are no dietary or medication restrictions required.
- For most people, it takes about 15-30 minutes to collect their sample.
- No need for scheduling appointments or taking time off from work.
- Reach out to LetsGetChecked to get your free hemoglobin A1C screening kit.
- Your kit includes everything you need to collect your sample from home.


Attachment 3 – Sample Communications

Welcome (‘In-Kit’) Letter

CLIENT COMPANY LOGO 

Putting your health first just got easier

CLIENT COMPANY LOGO 




Complete your A1C test

The enclosed A1C collection kit is provided through a partnership between [Client] and LetsGetChecked at no cost to you. It takes just a few minutes to complete.

The A1C test measures your average blood sugar level over the past three months. The test is used to determine your risk of diabetes and prediabetes or how well your diabetes is being managed.

This easy-to-use test kit comes with everything you need to collect your blood sample from home. It even comes with free return shipping to the lab.

How to get started

 <p>Plan to take your test in the morning, on a weekday. Drink a big glass of water before starting.</p>	 <p>Follow the step-by-step instructions in the box or scan this QR code to watch a video. [link]</p>	 <p>Return your sample on the same day using the prepaid return envelope.</p>
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Did you know?

About 1 in every 10 Americans has diabetes. 1 in 5 of them don't know it. Diabetes can be managed, so it's important to test to understand your risk. Take care of your health now and complete an A1C test. We'll send your result to you and your primary care provider (PCP) on file.

We're here to help

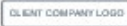

Call us if you have questions about this test at 1-XXX-XXX-XXXX (TTY 711), Monday through Friday, 8 a.m. to 8 p.m. ET.

Healthy regards,

LetsGetChecked in partnership with [Client]


Robert Mordkin, MD
Chief Medical Officer
LetsGetChecked

Announcement Letter

Your free sample collection kit is on its way.

Making it easier to measure your average blood sugar levels.




Hello [First Name],


[Client] has partnered with LetsGetChecked to help you stay up to date with health screenings. You will be receiving an at-home sample collection kit to complete an **A1C test** at no cost to you. The kit is on its way or already at your home.

It takes just a few minutes to collect your sample. No doctors or lab appointments either. Your kit includes everything you need to collect your sample from home.


More about the A1C (also called HbA1c) test:



The A1C test measures your average blood sugar level over the past 3 months. It shows how well your blood sugar is controlled over time.



It needs a blood sample that you can collect from home using a simple finger prick.



You send the blood sample to our lab (for free) to have it analyzed, and we'll send you [and your PCP] the results.



We're here to help

Call us if you have questions about this test at 1-XXX-XXX-XXXX (TTY 711), Monday through Friday, 8 a.m. to 8 p.m. ET.

Healthy regards,


LetsGetChecked in partnership with [Client]

Kit Return Reminder Letter

How to return your sample

Scan this QR code with your phone's camera to watch a helpful video.




Hello [First Name],


Our lab hasn't received your blood sample for your A1C test. Do you have any questions or need help?

The A1C test is important. It measures your average blood sugar level over the past 3 months to tell you how well your blood sugar is being controlled over time. This can be an indicator of your risk for diabetes or how well your diabetes is being managed. It can help you decide if you need to adjust your diet, exercise, and/or treatment plan.


Remember:



Your kit includes everything you need to collect your sample from home.



Drink a big glass of water before collecting your sample to stay hydrated.



LetsGetChecked's care team is ready to help you if you need us.

Collect your blood sample and return it to our lab (postage-free) this week.

We're here to help

Call us if you have questions about this test at 1-XXX-XXX-XXXX (TTY 711), Monday through Friday, 8 a.m. to 8 p.m. ET.

Healthy regards,

LetsGetChecked in partnership with [Client]