



**Grifols Laboratory  
Solutions Inc.**  
Directory of Services

Grifols is a global healthcare company that since 1909 has enhanced the health and well-being of people around the world.

Grifols Laboratory Solutions Inc. provides industry-leading diagnostic solutions for clinical issues related to Molecular and Serological Immunohematology. We provide testing, consultation, and integrated solutions to optimize patient care for specialists in Hematology, Oncology, Perinatology, Obstetrics, Pharmacy, Transplantation, and Transfusion Medicine.



CLIA License #45D2099571, CAP Certificate #9406144, AABB Accreditation #1751090

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**Menu of  
Services**

# Frequently Ordered Tests

## BGG Navigator Panels

PRODUCT #	TEST	ANTIGENS TARGETED	PLA/CPT® CODE *	DESCRIPTION/APPLICATION
9009367	BGG Navigator Panel	Multiple antigen red cell panel	0084U	<ul style="list-style-type: none"> <li>• Pretreatment with mAB therapy (CD38/47)</li> <li>• Prospective antigen matching for multiply transfused patients with hemoglobinopathies (eg, sickle cell)</li> <li>• Serologic testing complications due to recent transfusion or autoantibodies</li> </ul>
9009368	BGG Navigator Workup	Multiple antigen red cell panel +	0084U+	This solution begins with the BGG Navigator Panel and reflexes to additional Molecular and Immunohematology tests to resolve a complex patient case
9009828	Molecular Donor Panel (37 Antigens)			ID CORE XT blood group genotyping multiplex DNA analysis 37 antigens of 10 blood groups: RHCE, Kell, Kidd, Duffy, MNS, Diego, Dombrock, Colton, Cartwright, and Lutheran

## Navigator Blood Group Gene Sequencing

PRODUCT #	TEST	ANTIGENS TARGETED	PLA/CPT® CODE *	DESCRIPTION/APPLICATION
9008615	RHD Variants Including Weak D 1,2,3,4 Sequencing	RhD	0198U	<ul style="list-style-type: none"> <li>• RhD discrepancies</li> <li>• RhD status for RhIG eligibility</li> <li>• RhD+ with anti-D</li> </ul>
9007417	ABO Sequencing	A,B,O	0180U	<ul style="list-style-type: none"> <li>• Resolve ABO blood grouping discrepancies</li> <li>• Subgroup of A transplant eligibility</li> </ul>

## Human Platelet Antigen Genotyping

PRODUCT #	TEST	ANTIGENS TARGETED	PLA/CPT® CODE *	DESCRIPTION/APPLICATION
9009379	HPA-1 Genotyping	HPA-1	81105	Analysis of the coding sequence and splice sites of exon 3 of the ITGB3 gene to predict the HPA-1 phenotype
9009864	HPA Genotyping	HPA-1 HPA-2 HPA-3 HPA-4 HPA-5 HPA-6 HPA-9 HPA-15	81105 81106 81107 81108 81109 81110 81111 81403	Alloimmune thrombocytopenia
9009378	HPA Genotyping Panel	HPA-1 HPA-2 HPA-3 HPA-4 HPA-5 HPA-6 HPA-7 HPA-8 HPA-9 HPA-10 HPA-11 HPA-15	81105 81106 81107 81108 81109 81110 81403 81403 81111 81403 81403 81403	Platelet refractoriness

# Molecular Tests

## Navigator Sequencing Tests (performed using Sanger sequencing unless otherwise indicated)

PRODUCT #	TEST	ANTIGENS TARGETED	PLA/CPT® CODE*	DESCRIPTION
9007417	<a href="#">ABO Sequencing</a>	A,B,O	0180U	Resolve ABO blood grouping discrepancies and Subgroup of A transplant eligibility
9008755	<a href="#">CO Sequencing</a>	Colton	0181U	Analysis of the coding sequence and splice sites of the CO gene to predict the Colton phenotype
9009369	<a href="#">CROM Sequencing</a>	Cromer	0182U	Analysis of the coding sequence and splice sites of the CROM gene to predict the Cromer phenotype
9008753	<a href="#">DI Sequencing</a>	Diego	0183U	Analysis of the coding sequence and splice sites of the DI gene to predict the Diego phenotype
9008754	<a href="#">DO Sequencing</a>	Dombrock	0184U	Analysis of the coding sequence and splice sites of the DO gene to predict the Dombrock phenotype
9008758	<a href="#">FUT1 Sequencing</a>	A,B,H	0185U	Analysis of the coding sequence and splice sites of the FUT1 gene to determine if H antigen is produced
9008759	<a href="#">FUT2 Sequencing</a>	A,B,H	0186U	Analysis of the coding sequence and splice sites of the FUT2 gene to determine if A, B, and H antigens are secreted
9008749	<a href="#">FY Sequencing</a>	Duffy	0187U	Analysis of the coding sequence and splice sites of the FY gene to predict the Duffy phenotype
9009370	<a href="#">GE Sequencing</a>	Gerbich	0188U	Analysis of the coding sequence and splice sites of the GE gene to predict the Gerbich phenotype
9008747	<a href="#">GYPA Sequencing</a>	M,N	0189U	Analysis of the coding sequence and splice sites of the GYPA gene to predict the expression of M and N phenotypes
9008748	<a href="#">GYPB Sequencing</a>	S,s,U,Mia	0190U	Analysis of the coding sequence and splice sites of the GYPB gene to predict the expression of S, s, U, and Mia phenotypes
9009371	<a href="#">IN Sequencing</a>	In	0191U	Analysis of the coding sequence and splice sites of the IN gene to predict the Indian phenotype
9008745	<a href="#">JK Sequencing</a>	Kidd	0192U	Analysis of the coding sequence 5'UTR and splice sites of the JK gene to predict the Kidd phenotype
9008751	<a href="#">JR Sequencing</a>	Jra	0193U	Analysis of the coding sequence and splice sites of the JR gene to predict the expression of the Jra phenotype
9008743	<a href="#">KEL Sequencing</a>	Kell	0194U	Analysis of the coding sequence 5'UTR and splice sites of the KEL gene to predict the Kell phenotype
9008744	<a href="#">KLF1 Sequencing</a>	Lutheran	0195U	Analysis of the coding sequence and splice sites of the KLF1 gene to the In(Lu) phenotype
9008746	<a href="#">LU Sequencing</a>	Lutheran	0196U	Analysis of the coding sequence and splice sites of the LU gene to predict the Lutheran phenotype
9008860	<a href="#">LW Sequencing</a>	LW	0197U	Analysis of the coding sequence and splice sites of the LW gene to predict the Landsteiner-Wiener phenotype
9009372	<a href="#">RH Sequencing (NGS)</a>	RhD and RhCE	0222U	Analysis of the coding sequence, selected intron sequences, proximal promoter, and splice sites of the RHD and RHCE genes to predict the Rh phenotypes
9007420	<a href="#">RHCE Sequencing</a>	RHCE	81403	Analysis of the coding sequence and splice sites of the RHCE gene to predict the Rhce phenotypes

## Navigator Sequencing Tests *(continued)*

PRODUCT #	TEST	ANTIGENS TARGETED	PLA/CPT® CODE*	DESCRIPTION
9008615	RHD Variants Including Weak D 1,2,3,4 Sequencing	RhD	0198U	<ul style="list-style-type: none"> <li>• RhD discrepancies</li> <li>• RhD status for RhIG eligibility</li> <li>• RhD+ with anti-D</li> </ul>
9007418	RHD Zygosity	RhD	0222U	Quantitative analysis of the RHD gene in a paternal sample in order to determine the risk of hemolytic disease of the fetus and newborn; Order RH Full Gene Sequencing
9008859	SC Sequencing	Sc	0199U	Analysis of exons 4 and 12 and their splice sites in the SC gene to predict the Scianna phenotype
9008739	Single Amplicon Sequencing		81401	Analysis of a single exon and splice sites (amplicon) for any blood group system gene to confirm the nucleotide sequence
9008750	XK Sequencing	Kx	0200U	The analysis of the coding sequence and splice sites of the XK gene to predict the Kx and Kell phenotypes
9008756	YT Sequencing	Cartwright	0201U	Analysis of the coding sequence and splice sites of the YT gene to predict the Cartwright phenotype
9009828	Molecular Donor Panel (37 Antigens)			ID CORE XT blood group genotyping multiplex DNA analysis 37 antigens of 10 blood groups: RHCE, Kell, Kidd, Duffy, MNS, Diego, Dombrock, Colton, Cartwright, and Lutheran

## HPA Genotyping Tests

PRODUCT #	TEST	ANTIGENS TARGETED	PLA/CPT® CODE*	DESCRIPTION
9009864	HPA Genotyping	HPA-1 HPA-2 HPA-3 HPA-4 HPA-5 HPA-6 HPA-9 HPA-15	81105 81106 81107 81108 81109 81110 81111 81403	Alloimmune thrombocytopenia
9009378	HPA Genotyping Panel	HPA-1 HPA-2 HPA-3 HPA-4 HPA-5 HPA-6 HPA-7 HPA-8 HPA-9 HPA-10 HPA-11 HPA-15	81105 81106 81107 81108 81109 81110 81403 81403 81111 81403 81403 81403	Platelet refractoriness
9009379	HPA-1 Genotyping	HPA-1	81105	Analysis of the coding sequence and splice sites of exon 3 of the ITGB3 gene to predict the HPA-1 phenotype
9009380	HPA-2 Genotyping	HPA-2	81106	Analysis of the coding sequence and splice sites of exon 2 of the GPIBA gene to predict the HPA-2 phenotype
9009381	HPA-3 Genotyping	HPA-3	81107	Analysis of the coding sequence and splice sites of exon 26 of the ITGA2B gene to predict the HPA-3 phenotype
9009382	HPA-4 Genotyping	HPA-4	81108	Analysis of the coding sequence and splice sites of exon 4 of the ITGB3 gene to predict the HPA-4 phenotype
9009383	HPA-5 Genotyping	HPA-5	81109	Analysis of the coding sequence and splice sites of exon 13 of the ITGA2 gene to predict the HPA-5 phenotype
9009384	HPA-6 Genotyping	HPA-6	81110	Analysis of the coding sequence and splice sites of exon 10 of the ITGB3 gene to predict the HPA-6 phenotype

## HPA Genotyping Tests *(continued)*

PRODUCT #	TEST	ANTIGENS TARGETED	PLA/CPT® CODE*	DESCRIPTION
9009385	HPA-7 Genotyping	HPA-7	81403	Analysis of the coding sequence and splice sites of exon 10 of the ITGB3 gene to predict the HPA-7 phenotype
9009386	HPA-8 Genotyping	HPA-8	81403	Analysis of the coding sequence and splice sites of exon 12 of the ITGB3 gene to predict the HPA-8 phenotype
9009387	HPA-9 Genotyping	HPA-9	81111	Analysis of the coding sequence and splice sites of exon 26 of the ITGA2B gene to predict the HPA-9 phenotype
9009388	HPA-10 Genotyping	HPA-10	81403	Analysis of the coding sequence and splice sites of exon 3 of the ITGB3 gene to predict the HPA-10 phenotype
9009389	HPA-11 Genotyping	HPA-11	81403	Analysis of the coding sequence and splice sites of exon 12 of the ITGB3 gene to predict the HPA-11 phenotype
9009390	HPA-15 Genotyping	HPA-15	81112	Analysis of the coding sequence and splice sites of exon 19 of the CD109 gene to predict the HPA-15 phenotype

**\*PLA and CPT code are registered trademarks of the American Medical Association.**

CPT® is a registered trademark of the AMA. The CPT codes identified herein are subject to change and are to be used for reference purposes only. They are not intended to be a comprehensive list or to replace authoritative coding guidebooks and references. Coding decisions are to be made based on the independent clinical judgment of the patient's qualified healthcare practitioner. It is the responsibility of the provider to identify and submit appropriate and accurate codes and modifiers for laboratory services rendered, and to ensure that all necessary supporting documentation is appropriately developed and maintained.

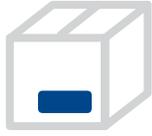
Laboratory Developed Test (LDT) - the performance characteristics of these tests were validated by the GLS Laboratory in San Marcos, TX, as authorized under Clinical Laboratory Improvement Amendments (CLIA) to perform high-complexity testing.

# Serology Tests

PRODUCT #	TEST	PLA/CPT® CODE*	DESCRIPTION
9008684	ABO Typing	86900	Direct agglutinating tests to determine the presence or absence of A and B antigens on red cells and ABO antibodies in serum or plasma
9008685	Rh(D) Typing	86901	Direct agglutinating test to determine the presence or absence of RhD antigen on red cells
9008686	Weak D Typing	86901x4	Inidirect antiglobulin test to determine the presence or absence of a weakly expressed RhD antigen on red cells
9008687	Antibody Screen	86850	Test using ≤3 reagent red cells (screen) to detect unexpected autoantibodies and alloantibodies to non-ABO blood groups in serum or plasma
9009782	Cell rule-out (screen)	86850	Specifically selected (≤3) reagent red cells used to rule out alloantibodies in serum or plasma
9009783	Cell rule-out (panel)	86870	Specifically selected (4 to 11) reagent red cells used to rule out alloantibodies in serum or plasma
9008710	DAT	86880	Test to determine if red cells have been sensitized in vivo with IgG and/or complement
9008689	Antibody Panel	86870	Test using 4 to 11 reagent red cells (panel) to identify unexpected autoantibodies and alloantibodies to non-ABO blood groups in serum or plasma
9008690	Rare Cell Rule-out Panel	86870	Specifically selected (any number) rare reagent red cells to identify or rule out alloantibodies in serum or plasma, eg, red cells negative or positive to high or low prevalence antigens.
9008691	Antibody Titer	86870	Semi-quantitative test to determine antibody levels in serum or plasma
9008692	Elution	86860	Technique to dissociate autoantibodies or alloantibodies from red cells
9009827	Antigen Typing (Rh phenotyping)	86906	Test to determine the presence or absence of the common antigens in the Rh blood group system (C, E, c, e excluding RhD) on red cells using antisera
9008695	Antigen Typing (per antigen)	86905	Test to determine the presence or absence of non-ABO blood group antigens on red cells using antisera
9008696	Antigen Typing (Lectin, per antigen)	86905	Test to determine the presence or absence of blood group antigens on red cells using lectins
9008697	Antigen Typing (Rare, per antigen)	86905	Test to determine the presence or absence of rare blood group antigens on red cells using rare antisera or well-characterized rare alloantibodies in serum or plasma
9008698	Adsorption, Allo	86978	Technique to adsorb autoantibodies or alloantibodies from serum or plasma using allogeneic red cells
9008699	Adsorption, Auto (Warm or Cold)	86978	Technique to adsorb autoantibodies from serum or plasma using autologous red cells
9008702	Neutralization (per target)	86977	Technique using soluble antigens or ligands to neutralize an antibody reactivity
9008703	RBC Enzyme Treatment (per enzyme)	86877	Enzyme treatment of red cells to affect the detection of blood group antigens
9008704	Pretreatment of RBCs for Testing (per treatment)	86970	Chemical treatment of red cells to affect the detection of blood group antigens
9008705	Pretreatment of Serum/Plasma for Testing (per treatment)	86977	Chemical treatment of serum or plasma to affect the reactivity of antibodies



# Easy Order Process



## 1 Registration and Ordering Kits

**Register and request a sample-collection kit.** Email us at [infolab@grifols.com](mailto:infolab@grifols.com), or call: +1 (833) 504-1609.

- Your login credentials for our Path-tec portal at [spectrapath.grifols.com](http://spectrapath.grifols.com) will be emailed to you.
- Your kit will arrive in one to five business days. Store kit at room temperature.



## 2 Sample Collection

**Collect the patient sample and complete the requisition form from the kit.** Keep a copy for your records. Follow collection instructions for each test, since kits and instructions vary.

- See sample-handling requirements, detailed in Appendix 2.
- Isolated nucleic acid/extracted DNA samples can only be accepted if prepared in a CLIA-certified laboratory. Please provide the lab's CLIA number with submission.
- If not using provided kits, please download requisition forms at [diagnostic.grifols.com](http://diagnostic.grifols.com); click on the link for "Testing Services" and follow the instructions. Keep a copy for your records.



## 3 Sample Preparation for Shipping

**Label tubes with patient ID labels printed with two patient identifiers.** Prepare for shipping to the GLS laboratory.

- For shipping, secure the kit inside the clinical pack; seal in return envelope provided; and schedule UPS pickup. Refer to sample-handling requirements, Appendix 2, for details.



## 4 Results Reporting

**Receive the full results report by encrypted email within the expected turnaround time post receipt of sample.**

- Test results can be provided both to the clinical care team for entry into the medical record in advance of treatment decisions\* and to Blood Bank LIMS.



## 5 We Take Care of Billing

**GLS Laboratory bills Medicare or certain other payers, when appropriate.**

- You focus on getting your patient started with the best, most results-informed therapy as part of a patient-centered and quality-driven approach to care.

\*Please note: Providers should follow their institutions' EMR entry procedures for laboratory test results. Grifols does not guarantee proper results upload to the EMR.

# Sample Handling Requirements

## Sample Collection

SPECIMEN	VOLUME/AMOUNT	CONTAINER	ADDITIONAL INFORMATION
<b>Molecular Testing</b>			
<b>BGG Navigator: Whole Blood</b>	-2mL	1 EDTA/Lavender	Samples must be received at GLS within 7 days after collection
<b>BGG Navigator: Genomic DNA</b>	3 µg at ≥ 20 ng/µL, A <sub>260</sub> /A <sub>280</sub> : 1.65-1.95, A <sub>260</sub> /A <sub>230</sub> ≥ 1.5	1.5 mL micro-centrifuge tube, Eppendorf preferred	Samples must be received at GLS within 14 days after collection. DNA must be dissolved in water or a low-salt buffer
<b>BGG Navigator: Buccal Swab</b>	Follow collection instructions on the package label	oracollectDx® OCD-100	Samples must be received at GLS within 14 days after collection
<b>BGG Navigator Resolution Workup</b>	-10 mL 20 mL	2 EDTA/Lavender 3 Plain red top	BGG Navigator plus gene sequencing plus phenotyping and antibody ID as required
<b>Molecular Donor Panel (37 antigens)</b>			Call for special collection instructions
<b>Blood Group Gene Sequencing (any)</b>	-2 mL	1 EDTA/Lavender	

## Serology Testing (Do NOT use tubes containing gel separators)

<b>ABO/RhD (including weak D) and DAT</b>	-5 mL	1 EDTA/Lavender	
<b>RBC Antigen Phenotyping</b>	-5 mL	1 EDTA/Lavender	
<b>Antibody Identification Problem</b>	-5 mL 20 mL	1 EDTA/Lavender 3 Plain red top	4 – 6 mL blood bank EDTA tubes 3 x 7 mL or 2 x 10 mL plain red top tubes
<b>Antibody Titer</b>	-5 mL 20 mL	1 EDTA/Lavender 3 Plain red top	4 – 6 mL blood bank EDTA tubes 3 x 7 mL or 2 x 10 mL plain red top tubes
<b>Daratumumab Serologic Workup</b>	-10 mL 20 mL	2 EDTA/Lavender 3 Plain red top	4 – 6 mL blood bank EDTA tubes 3 x 7 mL or 2 x 10 mL plain red top tubes
<b>Warm Autoimmune Hemolytic Anemia Workup: If not transfused within past 3 months</b>	-20 mL 10 mL	4-5 EDTA/Lavender 1 Plain red top	4 – 6 mL blood bank EDTA tubes 1 x 7 – 10 mL plain red top tube
<b>Warm Autoimmune Hemolytic Anemia Workup: If transfused within the past 3 months</b>	-5 mL 20 mL	1 EDTA/Lavender 3 Plain red top	4 – 6 mL blood bank EDTA tubes accepted 3 x 7 mL or 2 x 10 mL plain red top tubes
<b>Cold Agglutinin Screen and Titer</b>			Call for special collection instructions

## Sample Storage and Transportation

(For Serology testing, contact the lab by phone or email that a blood sample is in transit.)

SPECIMEN	CONDITIONS
<b>Whole Blood</b>	Samples should be shipped priority overnight; refrigerated (2 to 8°C) or at room temperature (15 to 24°C).
<b>Genomic DNA</b>	Samples should be shipped priority overnight; frozen, refrigerated (2 to 8°C), or at room temperature (15 to 24°C).
<b>Buccal Swab</b>	Samples can be shipped at room temperature (15 to 24°C).

# Supplies & Shipping Portal

## Setting Up a Supplies & Shipping Portal

A Grifols portal manager will set up your initial administrative access to create new users, update passwords, and grant access rights for your staff.

**If you are a new customer needing to register,** please contact us at +1 (833) 504-1609 or via email at [infolab@grifols.com](mailto:infolab@grifols.com).

To set up a customer unique access, log into [spectrapath.grifols.com](http://spectrapath.grifols.com) with your username and password. Once you're logged into the site, you may begin placing orders.

To place an order, select the items you need and input the quantity in the Quantity field. Click Continue to review your order.

Once your order is submitted, you will receive a confirmation on the screen and via email.

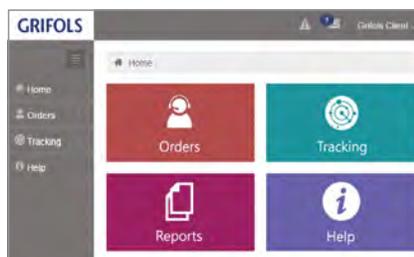
**Note:** If you need a username and password, please contact the help desk at [helpdesk@pathtec.com](mailto:helpdesk@pathtec.com).

### Step 1: Log In



Log into [spectrapath.grifols.com](http://spectrapath.grifols.com). If you need a username and password, please contact the help desk at [helpdesk@pathtec.com](mailto:helpdesk@pathtec.com).

### Step 2: Order Selection



The items available to order are listed on the screen. To order an item, input the quantity in the Quantity field. Click Continue to review your order.

If everything is correct, click Submit Order.

### Step 3: Order Confirmation



Category	Item #	Description	Quantity	Max Quantity	Price
Kit	4564-CD	Combined Study Kit E.A.	10		

Once your order is submitted, you will receive an order confirmation on the screen and via email.

# Customer Billing Portal

## Setting Up a Customer Billing Portal

A Grifols portal manager will set up your initial administrative access to create new users, update passwords, and grant access rights for your staff.

**If you are a new customer needing to register,** please contact us at +1 (833) 504-1609 or via email at [infolab@grifols.com](mailto:infolab@grifols.com).

As administrator, you will want to define the rights of the new user defined by their roles.

A new user is defined by their email.

If the “Force User to Change Password Upon Next Login” option is selected, the user will have to change their password the first time they log in.

**Note:** Please reference the Help for additional information.

### Step 1: Access the Customer Billing Portal via the following URL



### Step 2: Log into the Client Portal

A screenshot of the 'Client Portal Login' form. It has two input fields: 'User' with the value 'dland@customername.com' and 'Password' with masked characters. A blue 'Login' button is at the bottom right. A blue arrow points from the text on the right to the 'User' field.

The user name must be in **email format**. It does not need to be an active email account—it just needs to look the part.

### Step 3: New User Set-Up and Access Rights

A screenshot of the 'User Administration' page. The top navigation bar includes 'Client Portal Home', 'Client Invoices', 'Billing Assignment', 'Client Price Inquiry', and 'Administration'. Below the title, there is a 'User ID' input field with a search icon and a blue 'Load User' button with a right-pointing arrow.

The portal administrator will create the new user name in **email format**.

A screenshot of the 'User Administration' page, similar to the previous one, but the 'User ID' field now contains the email address 'johndoe@customername.com' and has a green checkmark icon to its right. A blue arrow points from the text above to the 'User ID' field.

## User Access Rights:

The screenshot displays the 'User Administration' page. On the left, the 'User Account' section includes fields for User ID (john.doe@customername.com), First Name, Last Name, and E-mail. Below this is the 'Notifications' section with checkboxes for 'Statement Creation' and 'Pending Billing Assignments'. The 'Password' section has a 'Change Password Now' checkbox and a 'Last Change Date' field. A password strength indicator states: 'A valid password consists of eight or more alphanumeric characters and must contain at least one letter and one number.' There are fields for 'New Password' and 'Confirm Password', and a 'Force User to Change Password Upon Next Login' checkbox. At the bottom are 'Reset' and 'Submit' buttons.

On the right, the 'Access' section shows 'Client Access' with a 'Client ID' dropdown menu. Below is the 'Screen Access' table for 'SNF ABC':

Screen Name	No Access	Read Only	Update
Client Price Inquiry	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>
Billing Assignment	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>
Client Invoices	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>
User Administration	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>
Reset Password	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>

A legitimate email account needs to be provided for the purpose of sending client statement notifications and/or pending billing assignment notifications.

Portal users may only be associated to one Client ID.

Role-specific access is given within this grid.

Portal Administrator will provide a temporary password here, and force user to change password upon initial (or next) login.

## Re-set or Change a Password:

The screenshot shows the 'Reset Password' dialog box. It contains a password strength indicator: 'A valid password consists of eight or more alphanumeric characters and must contain at least one letter and one number.' Below this are input fields for 'User ID', 'New Password', and 'Confirm Password'. At the bottom are 'Reset' and 'Submit' buttons.

At least one user in a portal user group will have "update" rights to manage passwords.



# **GLS Billing Policies**

# Patient Health Coverage

## Grifols Laboratory Solutions Inc.

### BILLING

### INSTRUCTIONS

#### **Institution/Client Bill**

Will bill the institution/client directly.

#### **Medicare, Medicare Advantage, and Tricare**

Will bill Medicare. Medicare will determine coverage and payment.

#### **Medicaid**

Will bill Medicaid where coverage is available. Contact us for availability.

#### **Private Health Insurance**

Will bill your health insurance directly. Your health insurance company will determine coverage and payment, as well as the amount for which you are responsible, such as copay or deductible, if any.

#### **Patient Billing & Non-Contracted Insurance Plans**

Will bill patients directly and for any non-covered services, copayments, deductibles, or co-insurance balances as indicated by their insurer on the EOB or RA.



# Provider and Patient Requirements

**In all test ordering scenarios, the ordering provider must attest to the following on the Grifols Laboratory Solutions Inc. test requisition:**

- This requisition constitutes an order for testing from Grifols Laboratory Solutions Inc. I certify (a) the services are medically necessary and will assist me in treating my patient, (b) I maintain and will make available patient medical records documenting the foregoing, (c) I have supplied information to the patient regarding this testing and the patient has consented to genetic testing.
- Regarding patient consent, the ordering physician will be solely responsible for confirming that legally effective informed consent has been obtained from the patient or their authorized representative as required by applicable state law.
- By ordering a test from Grifols Laboratory Solutions Inc., the physician certifies that consent is in place and that test results will be used and disclosed only in accordance with applicable law.
- You have signed statements on file from the patient and in accordance with your practice or institution permitting you and your contracted vendors to release data to other organizations to adjudicate claims.

# Terms and Definitions

TERM	DEFINITION
<b>ACH</b>	Electronic wire transfer
<b>AMA</b>	American Medical Association, the group that is responsible for creating and maintaining CPT codes and their descriptions
<b>CMS</b>	Centers for Medicare and Medicaid Services, the government agency that provides health insurance for those over age 65 as well as those with disabilities. They also create national policy for state Medicaid and share with the states in funding the Medicaid program
<b>CPT</b>	Current Procedural Terminology — structure and codes owned, managed, and registered trademark of the AMA
<b>ICD-10</b>	International Classification of Diseases, version 10 is a medical diagnosis code used to classify diseases and a wide variety of signs, symptoms, abnormal findings, complaints, social circumstances, and external causes of injury or disease
<b>LCD &amp; LCT</b>	Local coverage determination and local coverage tests — policies created by Medicare administrative contractors, of which there are seven across the U.S. (the LCT are the tests referenced in LCDs)
<b>LSA</b>	Laboratory service agreement
<b>NCD</b>	National coverage determination — CMS policies that determine what tests and procedures it will pay for and defines which patients and their conditions for which the procedure or service is justified
<b>NPI</b>	National provider identifier — a 10-digit unique number that all covered healthcare providers and plans participating in Medicare, Medicaid, and private insurance must use in their financial transactions (as per HIPAA)
<b>OIG</b>	Office of Inspector General — specific to Health and Human Services, the office that oversees matters related to Medicare and other U.S. health agencies
<b>OPPS</b>	Outpatient prospective payment system — rules of the road to get reimbursed by CMS for outpatient procedures provided to patients they cover
<b>PLA</b>	Proprietary laboratory analyses (like CPT, a registered trademark of the AMA) — codes set within the CPT coding structure

# Patient Data and Information Necessary for Billing

FIELD NAME	INSTRUCTIONS
<b>Provider Name and Contact Information</b>	Provide the name and service location of the ordering clinician. Enter information in this format: Line 1: Provider name; Line 2: Street address; Line 3: City, State, ZIP code (Use standard state abbreviation and valid ZIP code); Line 4: Telephone; Fax; Country code; Line 5: Email address.
<b>Clinician's National Provider Identifier (NPI) Number</b>	Provide the 10-digit NPI number and name of the attending or referring provider.
<b>Patient Name/Identifier</b>	This is the patient identifier as assigned by the insurance company. (Report if number is different from the subscriber/insured's ID.)
<b>Patient Name</b>	We need the patient's last name, first name, and middle initial.
<b>Patient Address</b>	We need the patient's complete mailing address, including street number and name or P.O. box or RFD; city; state; ZIP code.
<b>Patient Birth Date</b>	We need the patient's date of birth in MMDDYYYY format.
<b>Patient Gender</b>	Use M for male, F for female, O for Other.
<b>Insurance Card Scan</b>	Provide a scan/pdf (both sides) of the patient's insurance card.
<b>Insurance Holder Name if Other Than Patient</b>	Indicate the insurance subscriber's last name, first name, and middle initial and relationship to the patient.
<b>Payer/Insurer Names</b>	Provide all payers in order of their liability, from whom some payment may be received for this claim. Enter the appropriate source of payment alpha code for each.
<b>Release of Information on File?</b>	Check the box accordingly if you have a signed statement on file permitting you and your contracted vendors to release data to other organizations to adjudicate the claim.
<b>Diagnosis Codes</b>	Provide the complete list of ICD-10-CM codes that are relevant to the patient's condition.

# Client Billing Policies

## **Our Responsibility**

Your account will be billed on the first of every month, unless other arrangements have been made. Invoices will be for contracted amounts, as documented in the LSA. If no contracted fee arrangement exists, we will charge the list price in our current list fee schedule (available upon request).

## **Your Responsibility**

- 1** You agree to compensate us by payment of check, certified money order, electronic wire transfer (ACH), credit card, or other approved form of payment method, within 30 days of the date of each Grifols IHC invoice – after which any undisputed unpaid invoice amount would be overdue. Interest may be assessed for any balances that remain outstanding after 30 days in accordance with the LSA.
- 2** We may provide some coding guide information based on material from the AMA; however, it is your responsibility to stay current on the applicable codes and any reimbursement changes, and to verify the accuracy of the codes used for billing purposes.

## **Additional Things You Should Know**

This Grifols Directory of Services describes the services and lists the tests we offer. AMA's CPT, including PLA codes, are available through the AMA and from many insurance carriers. The CPT codes are subject to change at any time. Coding for reimbursement is the sole responsibility of the billing party. Please direct any questions regarding coding to the payor being billed.

In some instances, tests performed may require additional charges, such as processing fees, stat testing, or reflexes. We may bill you for these.

Many states have enacted price, transparency statutes, and regulations requiring disclosure of healthcare-related fees and practices that sometimes lead to unexpected costs. Our list fee schedule and policies are available upon request.



# Policies for Medicare Plans and Tricare

## Our Responsibility

- 1** As per the Medicare OPPS molecular testing date-of-service rules, if we perform the test, we must bill Medicare for clinical molecular pathology laboratory services. (Hospitals and blood banks are not permitted to bill Medicare for any such tests they do not perform. Tricare also follows the CMS molecular testing date-of-service rules. So for eligible services and clients, we will bill Medicare, Medicare Advantage plans, and Tricare directly.)
- 2** When CMS molecular testing date-of-service rules and requirements do not apply, we will bill you for testing. Typically, these direct-billing categories would include testing for registered hospital patients (inpatients or outpatients) or for other hospitals' patients referred to you, and possibly others.
- 3** We will advise you of new LCD or updates whenever they are issued.

## Your Responsibility

- 1** When ordering tests for Medicare patients, physicians or authorized individuals should only order tests that are medically necessary for the diagnosis and treatment of a patient, rather than for screening purposes. The OIG takes the position that a physician who orders medically unnecessary testing may be subject to civil penalties.
- 2** Please check the appropriate billing box on the test requisition form or electronic order screen and make sure to fill in the form completely with ALL patient and provider information (see Appendix 1). Make sure to include your NPI number.
- 3** Please provide the ICD codes that most accurately describe the patient's condition.

## **What You Should Know About Medicare Rules**

The CMS molecular testing date-of-service rules and relevant criteria became effective January 1, 2020. Clinical diagnostic laboratory tests are reimbursed based on the current, annual national fee schedule published by CMS.

**The following procedures are exempted from fee schedule reimbursement:**

- Pathology consultations and written interpretations
- Blood bank services and serology testing

## **Why Do You Need to Include Medical Necessity Documentation and ICD-10 Codes?**

Medicare contractors require medical necessity documentation to determine coverage for tests that are subject to a NCD or LCD. A carrier will deny coverage for a LCT when it is submitted without specific diagnosis information that supports the medical necessity for the testing. Documentation of medical necessity for laboratory tests is reported to the carrier with an ICD-10 code. ICD-10 manuals are available from various publishers.

## **CMS Reimbursement Policies**

CMS has implemented uniform national coverage and administrative policies for clinical laboratory services, subject to NCD that ensure the medical necessity of certain services rendered to Medicare beneficiaries. CMS also allows Medicare contractors to develop their own LCD policies that vary among Medicare carrier jurisdictions. Many of the procedures subject to NCD or LCD are for clinical laboratory testing (LCTs).

## **Why Do We Ask for Patient, Provider, and Insurance Information?**

For tests performed on samples from patients enrolled in Medicare Advantage or Medicaid managed care plans, we will use the insurance card information provided to bill the plans for testing performed on behalf of beneficiaries pursuant to policies regarding non-contracted and contracted insurance.

# Policies for Billing Patients, Contracted, and Non-Contracted Insurance

## **Our Responsibility**

- 1** If requested, or as required by law, we will bill patients directly within the United States. In this case, the list fee schedule will apply (available upon request).
- 2** When appropriate, we will bill the patient upon receipt of a claim rejection. Insurance plans are billed at the same prices billed to patients. We will also bill any applicable deductibles, copayments, and coinsurance to the patient or, if applicable, their supplemental insurance plan.
- 3** In cases where we bill the insurer on the patient's behalf, we will contact you for required diagnosis information to file the claim since we cannot accept a diagnosis from the patient.

## **Your Responsibility**

- 1** Please check the appropriate billing box on the test requisition form or electronic order screen and make sure to fill in the form completely with ALL patient information (Appendix 1). Make sure to include the provider's NPI number.
- 2** Please contact your sales representative for an up-to-date list of our participating insurance plans.
- 3** Please provide the applicable diagnosis information from an ICD-10 code manual and request that we bill the insurance carrier.

## **Patient Fees**

Fees charged directly to patients vary from those charged to physicians/clients. Panels and/or profiles that do not conform to specific CPT codes will be billed as the individual test components performed.

## **Patient Billing Process**

Upon receipt of notice of the non-contracted insurer's adjudication of the claim and payment by the insurer for the amount due from the insurer, the billing vendor will send a letter to the patient, accompanied by a bill for the amount representing the patient's obligation.

## **Process for Certain Non-Contracted Blue Payers**

For any non-contracted Blue payer (eg, certain Anthem and Blue Cross and Blue Shield plans) the billing vendor will send the patient a letter indicating that the patient may be receiving a check from their insurer and to forward that check to GLS. If after a patient's insurance carrier adjudicates a claim, the billing vendor determines that the insurer has sent payment directly to the patient rather than to Grifols – the billing vendor will send a bill for the amount representing the paid to patient amount (if known) and any additional patient obligation.

This describes what our practices are when claims have been rejected by an insurance carrier, as well as a typical scenario and our response when a patient's insurance carrier is one with whom we don't currently have a contracted relationship.



## **Accreditations and Licenses**

**Accreditations**

BODY	MEMBER NUMBER
CLIA	45D2099571
CAP	9406144
AABB (Molecular)	1751090

**Licenses**

BODY	MEMBER NUMBER
California	CDS 00800818
Maryland	2729
Pennsylvania	35890
Rhode Island	LCO01273

**GLS Regular Operating Hours**  
Monday through Friday  
8:00 am to 5:00 pm Central

# Enhancing the health and well-being of people around the world

**For further information, visit [www.diagnostic.grifols.com/testing-services](http://www.diagnostic.grifols.com/testing-services)  
or call +1 (833) 504-1609.**

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