LABORATORY SOLUTIONS

Hematologic Malignancies, Hemoglobinopathies, Sickle Cell Disease, and Anemias

BGGNAVIGATOR®

Proactive Genotyping

The global solution to navigate pretransfusion testing and the interference of monoclonal antibody therapies

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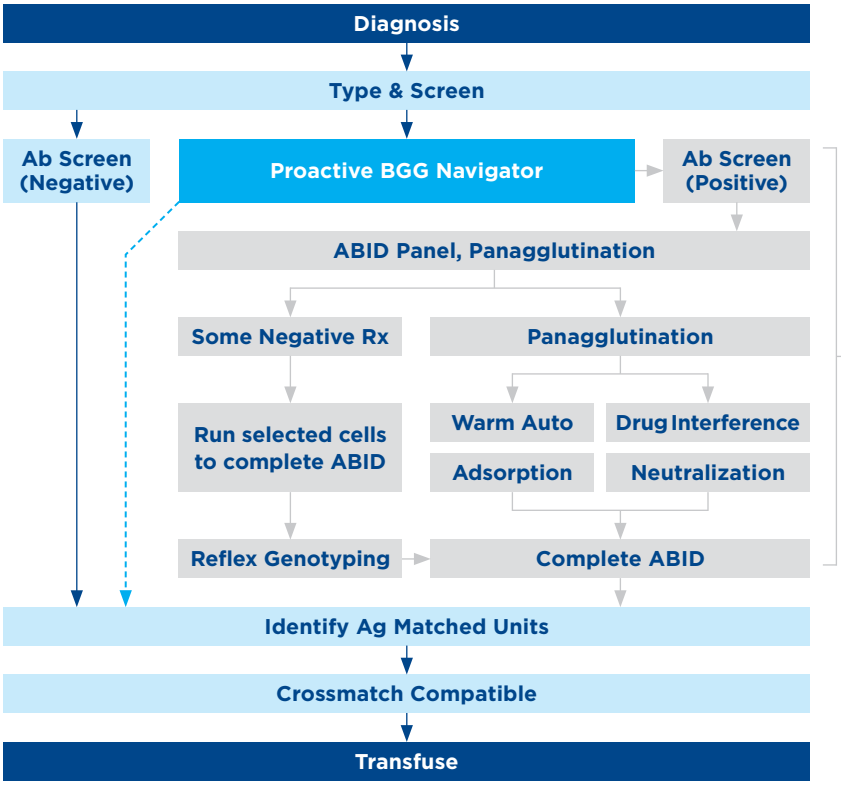
BGGNAVIGATOR®

BGG Navigator is the global solution to navigate pretransfusion testing and interference of monoclonal antibody therapies to overcome the challenges of delivering optimal patient care.

Clinical and operational challenges:

- **Proactive molecular blood group genotyping** can replace complicated, antiquated, repetitive, and costly testing algorithms with a single diagnostic solution to unite the needs of oncology, transfusion medicine, and pharmacy[18, 19, 20, 22]
- **Clinical, patient, compliance, and cost risks**[22]
  - Mitigate therapeutic delays
  - Provide best matched blood products
  - Reduce the risk of alloimmunization
  - Reduce re-hospitalization
  - CMS, commercial payor, FDA, and OIG compliant
- **Comprehensive antigen genotype** that cannot be obtained serologically due to availability or reliability of antisera[22]
- **The standard of care** at many institutions for patients being treated with immunotherapies, including anti-CD38/47[1, 2, 3, 22]
- **Meet ASH guidelines** for sickle cell disease to improve patient quality of life, outcomes, and cost of care[23]
- **Manage the cost impact** on oncology care models, hospital revenue, and patient's out-of-pocket expense via 108 covered ICD-10 Codes
- **Non-invasive specimen collection buccal swab**
  - Removes concerns with subcutaneous therapeutics
  - Eliminates inconvenience of phlebotomy and provides logistical flexibility to collect samples anywhere, including a patient's home or office

Proactive pretransfusion testing with BGG Navigator



Potential Serological Cost Avoidance*

DIAGNOSTIC CATEGORY**	PER PATIENT COST 2022
Autoimmune anemia	**$1,226.55**
Hematologic malignancies	**$627.20**
Transplant recipients	$458.80
Infection	$426.97
Hemoglobinopathies	**$442.88**
Rheumatologic/collagen vascular disease	$348.74
Renal insufficiency	$365.98
Other anemia	**$343.43**
Liver failure/hepatitis/cirrhosis	$330.17
Bleeding	$308.96
Vascular disease (not including coronaries)	$291.72
Diabetes	$299.68
Cardiovascular	$289.07
Solid tumor malignancies	$287.74
Non-transplant surgery	$238.68
Trauma	$184.31
Solid organ donor	$123.32
Obstetrics	$123.32
Neonatal ICU	$88.84

* Does not include additional ~$350 direct genotyping cost incurred by the hospital or patient.
** Diagnostic catgeories highlighted in blue represent coverage policies for 108 ICD-10 codes.

Oncology, pharmacy, and transfusion medicine share in opportunities to achieve the Quadruple AIM

Improve patient outcomes, experiences, and confidence, while maintaining compliance and avoiding costs.

Outcomes and Population Health

- Collect specimens in the outpatient setting to optimize integration of patient care plan before Oncology Care Models, Value Based Care Initiatives, and Quadruple AIM measures begin[21]
- Complies with FDA warnings[4], CMS Molecular Testing Guidelines[5] as well as AABB standard of care[6,22] and ASH guidelines[7]
- Supports Disparity in Health Care Initiatives for Sickle Disease[8] and Multiple Myeloma[15]

Lower Costs

- A proactive ordering in the outpatient setting is a covered benefit for Medicare, Medicare Advantage, and most commercial health plans and is supported by 108 medical necessity ICD-10 codes
- Proactive ordering is becoming the standard of care and an alternative to unrecoverable serology testing costs, labor, instrumentation, training, proficiency, and space allocation[18,19,20,22]

Improved Provider Experience

- Test results in the EHR unite the multi-disciplinary care team and health system through meaningful use, data portability, and transparency
- Confidence of patient safety through the reduction of ordering errors and duplication[9]
- Curtail risk and costs associated with hospital length of stay[10]

Improved Patient Experience

- BGG Navigator will most likely be ordered only once in a patient's lifetime and can be performed at any time during therapy[3,22]
- Improve quality of life by potentially reducing the frequency of transfusions[11,13]
- Improved patient/donor matching avoids alloimmunization risk[11,12,16,17,22]

Intended use: Proactive utilization of the assay for pretreatment with monoclonal antibody therapies (mAB) (CD38/47) or other interfering agents, prospective antigen matching for multiply transfused patients with hemoglobinopathies (eg, sickle cell), and serological testing complications due to prospective or recent transfusion and/or autoantibodies.

BGG Navigator testing provides a single efficient multiplex test to determine the blood group antigen profile of a patient either before treatment begins or even after anti-CD38/47 therapy has been initiated.

4 Steps to Successful Implementation

1	**Add to Patient Care Plan/EHR**	Unites the care team, removes the financial impact on oncology care models, and improves patient safety
2	**Proactive Ordering in the Outpatient Setting**	Reduces the risk of therapeutic delays and drives cost reductions for providers, hospitals, and patients
3	**Send Samples to Grifols Laboratory**	Actionable results and rapid turnaround times improve the clinician and patient experience
4	**Simultaneous Reporting/Repository**	Test results populate the EHR, while web-based access provides data portability for providers and patients

This information is for US customers only.
For customers outside of the US, contact infolab@grifols.com

Learn more about Grifols BGG Navigator at www.diagnostic.grifols.com

1 Cowan AJ, Green DJ, Kwok M, et al. Diagnosis and management of multiple myeloma: a review. JAMA. 2022;327(5):464–477. **2** Palumbo A, Avet-Loiseau H, Oliva S, et al. Revised international staging system for multiple myeloma: a report from International Myeloma Working Group. J Clin Oncol. 2015;33(26):2863-2869. **3** Lancman G, Arinsburg S, Jhang J, et al. Blood transfusion management for patients treated with anti-CD38 monoclonal antibodies. Front Immunol. 2018;9:2616. **4** Sarclisa. Accessed August 8, 2022. https://www.sarclisahcp.com **5** Laboratory date of service policy. CMS. Updated January 13, 2022. Accessed August 8, 2022. https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ClinicalLabFeeSched/Clinical-Lab-DOS-Policy **6** Regan DM, Markowitz MA. Mitigating the anti-CD38 interference with serologic testing. AABB. January 15, 2016. Accessed August 8, 2022. https://www.aabb.org/docs/default-source/default-documentlibrary/resources/association-bulletins/ab16-02.pdf **7** Westoff CM. Blood group genotyping. Blood.2019;133(17):1814-1820. **8** Lee L, Smith-Whitley K, Banks S, Puckrein G. Reducing health care disparities in sickle cell disease: a review. Public Health Rep. 2019;134(6):599-607. **9** Rodziewicz TL, Houseman B, Hipskind JE. Medical Error Reduction and Prevention. [Updated 2022 Jan 4]. In: StatPearls [Internet]. Treasure Island (FL): StatPearls Publishing; 2022 Jan-. Available from: https://www.ncbi.nlm.nih.gov/books/NBK499956/ **10** Chou ST, Alsawas M, Fasano RM, et al. American Society of Hematology 2020 guidelines for sickle cell disease: transfusion support. Blood Adv. 2020;4(2):327-355. **11** Carter JH, Flegel WA. Red cell transfusions in the genomics era. Semin Hematol. 2019;56(4):236-240. **12** Holmberg J. It's all in the genes—expanding molecular testing to improve healthcare for those with blood disorders. MLO. January 23, 2019. Accessed August 8, 2022. https://www.mlo-online.com/continuing-education/article/13017230/its-all-in-the-genesexpanding-molecular-testing-to-improve-healthcare-for-those-with-blood-disorders **13** Uhl, Lynne. Pretransfusion testing for red blood cell transfusion. UpToDate. Updated January 7, 2022. Accessed August 8, 2022. https://www.uptodate.com/contents/pretransfusion-testing-for-red-blood-cell-transfusion#H4979047 **14** Denomme GA, Anani WQ, Avent ND, et al. Red cell genotyping precision medicine: a conference summary. Ther Adv Hematol. 2017;8(10):277-291. **15** Ailawadhi S, Parikh K, Abouzaid S, et al. Racial disparities in treatment patterns and outcomes among patients with multiple myeloma: a SEER-Medicare analysis. Blood Adv. 2019;3(20):2986-2994. **16** Volkova E, Sippert E, Liu M, et al; Collaborative Study Group. Validated reference panel from renewable source of genomic DNA available for standardization of blood group genotyping. J Mol Diagn. 2019;21(3):525-537. **17** Sippert E, Volkova E, Rios M. Accuracy of blood group typing in the management and prevention of alloimmunization. In Erhabor O and Munshi A (eds). Human Blood Group Systems and Haemoglobinopathies. InTechOpen; 2021. Available from: https://www.intechopen.com/chapters/70038/ **18** Ramsey G, Zinni J, Sumugod RD, Lindholm PF. Utility of routine RBC genotyping for RBC alloantibody problems. Transfusion. 2014;54(suppl 2):47A-48A. **19** Al-Habsi KS, Shih AW, Barty R, et al. Red cell antigen genotyping compared to standard serological phenotyping in sickle cell disease patients in Canada: potential for reducing alloimmunization. Blood. 2015;126(23):3404. **20** Bedel BA, Halverson GR, Lough C, McCoy M, Carey PM. Integrating red cell molecular genotyping into the blood supply chain: how to manage with warm autoantibodies. Transfusion. 2016;56(supp 4):153A. **21** Flegel WA, Gottschall JL, Denomme GA. Integration of red cell genotyping into the blood supply chain: a populationbased study. Lancet Haematol. 2015;2(7):e282-289. **22** AABB news: the evolution of blood group genotyping. AABB. May 20, 2022. Accessed August 8, 2022. https://www.aabb.org/newsresources/news/article/2022/05/20/aabb-news-the-evolutionof-blood-group-genotyping **23** Anani WQ, Duffer K, Kaufman RM, Denomme GA. How do I work up pretransfusion samples containing anti-CD38? Transfusion. 2017;57(6):1337-1342.

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