

**Clinical Laboratory Fee Schedule Annual Laboratory Meeting
Agenda
Centers for Medicare & Medicaid Services
Tuesday, June 25, 2024***

This meeting provides a forum for the public to make presentations and submit written comments on new and reconsidered Clinical Laboratory Fee Schedule (CLFS) codes for the calendar year (CY) 2025 and provide comments on other specified CLFS issues (as applicable). Please note that only codes listed in our Clinical Laboratory Fee Schedule CY 2024 Updates file, located on the web at https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ClinicalLabFeeSched/Laboratory_Public_Meetings.html, will be addressed.

***IMPORTANT NOTE: Consistent with CMS' approach of prioritizing the health and safety of our employees and visitors, the CMS complex at 7500 Security Boulevard is closed due to an unforeseen building issue. Because of this, the CLFS Annual Laboratory Meeting scheduled for June 25, 2024, is being moved to a virtual-only platform and will not have in-person attendance.**

Note: Session times are approximate and subject to change. Teleconference connection details are provided using instructions described in Appendix A. The presentation list is provided in Appendix B.

AGENDA

- 8:30 a.m.** Check-In and Audio/Video Connection Test Check
- 9:00 a.m.** Welcome and Introductions
Rasheeda Arthur, PhD
Meeting Facilitator, Hospital and Ambulatory Policy Group, CMS
- 9:20 a.m.** **Public Presentations on CY 2025 New and Reconsidered Codes (Appendix B)**
***Note:** This session will contain 10-minute presentations from pre-registered presenters on specific CLFS codes with recommendations for either gap-filling or crosswalking for code payment determinations.
- 12:00 p.m.** Lunch Break
- 12:45 p.m.** **Public Presentations on CY 2025 New and Reconsidered Codes (Appendix B) (continued)**
- 5:00 p.m.** Closing and Meeting Adjourns

Appendix A: Instructions to access the webinar via Zoom:

Step 1: Please click the link below to join the webinar:

https://cms.zoomgov.com/webinar/register/WN_L41bQ8PTSKufwFqrpoktcg

Note: This link provides attendees the ability to view and listen to the meeting. Only confirmed presenters will have the ability to speak during the meeting.

Step 2: Before joining the meeting, all attendees and participants will be requested to provide their name and email address.

Step 3: Click “Register.”

Appendix B: List of presenters and codes to be reviewed.

#	Organization	Presenter	Code (s)
1	Mel-Mont Medical, Inc	Beverly Donehoo Gibson	0463U
1	Mel-Mont Medical, Inc	Bente Falang	0463U
1	Mel-Mont Medical, Inc	Alisa Tubbs	0463U
1	Mel-Mont Medical, Inc	Nilesh Dharajiya	0463U
1	Mel-Mont Medical, Inc	Frank Melendez	0463U
2	Quest Diagnostics	Joyce McAllister	0457U, 0355U
3	Labcorp	Margery Connelly	0468U
4	Pacific Edge Diagnostics USA LTD	David Sosa	0420U
4	Pacific Edge Diagnostics USA LTD	Tamer Aboushwareb	0420U
4	Pacific Edge Diagnostics USA LTD	Jordan Newell	0420U
5	Guardant Health	Mark McCoy	0422U
6	Abbott Molecular	Deborah Godes	0455U
7	Beckman Coulter Diagnostics	Deborah Godes	0427U
7	Beckman Coulter Diagnostics	Melissa Naiman	0427U
7	Beckman Coulter Diagnostics	Jerry L. Garner	0427U
8	DiaCarta Inc	Charles J. Rosser	0365U (removed)
9	ARUP/Mayo Clinic Laboratories/Quest	Cheryl James	86XX1
10	Variantyx Inc.	Shirel Weiss	0469U
10	Variantyx Inc	Joline Dalton	0469U
10	Variantyx Inc.	Christine M. Stanley	0469U
11	Cordgenics, LLC	Bruce Yeager	0435U
12	Pillar BioSciences Inc.	John Warren	0448U
13	Cardio Diagnostics, Inc.	John Warren	0439U, 0440U
14	Mayo Clinic Laboratories	Cheryl James	0430U, 0431U, 0432U, XX63U, XX65U, XX66U, 86041, 86043, 86366, 0446U, 0447U, 82XX0, 82XX1, 8X3X0, 8X3XX, 8X050, 8X051, 87XX0
15	MD Anderson Cancer Center	Melissa Robinson	88XX0
15	MD Anderson Cancer Center	Guilin Tang	88XX0
16	EntroGen, Inc	Gary Potikyan	0471U
17	ClearNote Health	Danielle W. Scelfo	XX91U
18	OncoHost, Inc.	Ofer Sharon	0436U
18	OncoHost, Inc.	Chris Dingman	0436U
19	Point of Care Testing Association (POCTA)	Mike Ryan	0427U, 8XX00, 87593
20	OpenDNA/Gene by Gene	Beverly Donehoo Gibson	0466U
20	OpenDNA/Gene by Gene	Eran Feldhay	0466U
21	Dartmouth Hitchcock Medical Ctr.	Wahab A. Khan	0413U
22	Geneoscopy, Inc.	Erica Barnell	0421U
23	Cepheid	Shivang Doshi	8XX00
24	Roche Diagnostics Operations, Inc.	Christina Arenas	0445U, 0459U
24	Roche Diagnostics Operations, Inc.	Maria-Magdalena Patru	0445U, 0459U
25	DiaCarta Inc.	Des O Leary	XX81U
26	Transplant Genomics Inc	Michelle Altrich	8156X
27	American Society for Microbiology (ASM)	Omai Garner	87593, 8X050, 8X051, 8XX00, 87XX0, 87XX1
28	Cytovale	Christopher Pfaff	0441U
29	C2N Diagnostics	Joel Braunstein	XX85U
30	Caris Life Sciences	Joel de Jesus	XX69U
31	Menarini Silicon Biosystems	Daryl Spinner	XX73U, XX74U, XX75U
31	Menarini Silicon Biosystems	Frank Kuhr	XX73U, XX74U, XX75U

#	Organization	Presenter	Code (s)
31	Menarini Silicon Biosystems	Sara Lazaro	XX73U, XX74U, XX75U
32	Lumos	Annie Bell	0442U
33	Coalition 21st Century	Mike Ryan	0420U, 0421U, 0422U, XX69U, XX78U, XX82U, XX91U
34	Natera, Inc.	Matthew Mega	XX78U & XX82U
35	Foley Hoag LLP, representing Abbott Molecular Diagnostics, Becton Dickinson, and Roche Diagnostics Operations, Inc.	Brian Carey	87XX1
36	ALZpath, Inc	Andreas Jeromin	XX62U
37	Cyted Health, Inc.	Stephanie Juniat	XX90U
37	Cyted Health, Inc.	Sarah Killcoyne	XX90U
38	Tempus AI, Inc	Nicole Sweeney	0473U, XX92U, XX95U, XX96U, XX97U
39	BioAgilytix Labs	Lars Björk	XX79U
40	Illumina Inc	Maude Champagne	0020M
40	Heidelberg Epignostix GmbH	David Jones	0020M
41	DiaCarta	Marina Bibikova	0465U
42	Prognetec Diagnostics, Inc	Eldon Jupe	0446U, 0447U
42	Prognetec Diagnostics, Inc	Melissa Munroe	0446U, 0447U
43	University of Rochester Medical Center	M. Anwar Iqbal	0454U
44	Exact Sciences Corporation	Mike Kemeter	0464U
44	Exact Sciences Corporation	Jorge Garces	0464U
44	Exact Sciences Corporation	Marilyn Olson	0464U
45	Phenomix Health	Dylan Kakos	X101U, X102U, X103U, X104U
46	Aventa Genomics	Chris Roberts	0444U
46	Arima Genomics	Anthony Schmitt	0444U
47	Promis Diagnostics, Inc.	Theo deVos	0452U
47	Promis Diagnostics, Inc.	Bo-Ram Bang	0452U
48	Association for Molecular Pathology	Victoria Pratt	81432, 81435, 81437, 8X050, 8X051, 8XX00, 87593, 87XX0, 87XX1, 0455U
49	Rady Children's Institute for Genomic Medicine	Russell Nofsinger	0425U, 0426U
49	Rady Children's Institute for Genomic Medicine	Madison Arenchild	0425U, 0426U
50	AdvaMedDx	Tara Burke	18 total: Microbiology/Infectious Disease: 87593, 8XX00 Genomic Sequencing Procedures: 0X00M Immunology: 82XX0, 82XX1, 8X3X0, 8X3XX, 83XX0 Proprietary Laboratory Analysis: 0422U, 0427U, 0445U, 0455U, 0459U, XX92U, XX95U, XX96U, XX97U, XX91U

#	Organization	Presenter	Code (s)
51	American Clinical Laboratory Association	Joan Kegerize	Path/Lab: 82XX0, 82XX1, 8X3X0, 8X3XX, 83XX0, 8X050, 8X051, 8156X, 0X00M, 8XX00, 87XX0, 88XX0, 87XX1, 86XX1, 87593 Molecular Pathology: 81432, 81435, 81437 Reconsidered Codes: 86041, 86042, 86043, 86366, 0355U, 0394U Proprietary Laboratory Analysis: 0421U, 0422U, 0427U, 0457U, 0468U, XX91U, 0455U, 0473U, XX92U, XX95U, XX96U, XX97U, 0445U, 0459U
52	Omnipathology Solutions Medical Corporation, Inc	Mohammad Kamal	0429U
53	GoPath Diagnostics	Jim Lu	0475U
54	BillionToOne Laboratory, Inc.	Oguzhan Atay	0449U, XX70U, XX71U, XX76U, XX77U
55	Genomind	Rob Dublin	0423U
56	Washington University School of Medicine	Rebecca O'Hearn	0443U