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Subcommittee on Antifungal Susceptibility Tests
Agenda and Summary Minutes
Saturday, 9 January 2016
Mission Palms Hotel
60 E 5th St, Tempe, Arizona

Meeting Title:	Subcommittee on Antifungal Tests	**Contact:**	mhackenbrack@clsi.org
Meeting Date:	Saturday, 9 January 2016		
Start Time:	9:00 AM Mountain (US) time	**End Time:**	4:30 PM
Meeting Purpose:	To conduct subcommittee business		
Requested Attendee(s):	All subcommittee members, advisors, and reviewers		
Actual Attendee(s):	B. Alexander, G. Procop, S. Cullen, P. Dufresne, J. Fuller, M. Ghannoum, K. Hanson, S. Lockhart, L. Ostrosky-Zeichner, D. Perlin, D. Shortridge, N. Wengenack, N. Wiederhold, L. Berkley, S. Brown, P. Conville, S. Das, T. Dingle, T. Dooley, R. Eusebio, G. Ewald-Saldana, G. Fine, T. Fritsche, B. Gancarz, D. Getsinger, B. Goldstein, A. Gray, M. Hackenbrack, P. Hogan, N. Holliday, J. Hejna, S. Killian, C. Knapp, L. Kovanda, J. Kus, B. Ling, J. Meis, M. Motyl, R. Mulder, S. Nambiar, D. Paisey, C. Pallotta, C. Pillar, R. Rennie, N. Robles, A. Schuetz, R. Shawar, S. Shinn, M. Traczewski, J. Turnidge, K. Van Horn, P. Verweij, M. Wal, H. Wang, S. Wood,		

AGENDA

Item	Time	Presenter	Description
1.	9:00 AM	B. Alexander	Opening remarks/Introductions
2.	9:10 AM	G. Fine	CLSI Update
3.	9:20 AM	M. Hackenbrack	Review of New CLSI Committee Structure and Voting Process
4.	9:40 AM	B. Alexander	Annual Subcommittee Update (Presentation) • Vote: 4 June 2015 meeting summary
	10:00 AM	Break	
5.	10:15 AM	B. Alexander	Review of ECV Antifungal Working Group Charter and Membership
6.	10:45 AM	B. Alexander	Review of ECVs approved for M57S – What's missing? (**Note:** At the meeting, this item was switched with Item #7)
7.	11:00 AM	S. Lockhart	Review of Data Requirements and Submission Form for ECV Analysis (**Note:** At the meeting, this item was switched with Item #6)
8.	11:20 AM	S. Lockhart	ECV data/*Cryptococcus* – amphotericin, flucytosine, fluconazole, voriconazole, itraconazole, posaconazole • Votes (?)
	12:00 PM	Luncheon	
9.	1:00 PM	S. Lockhart	ECV data/*Candida* - fluconazole, voriconazole, posaconazole
10.	1:15 PM	M. Ghannoum	ECV Educational Initiatives
11.	1:30 PM	B. Alexander	ECVs – Next Steps- M57S supplement revision
12.	1:45 PM	D. Perlin	Update from Caspofungin Working Group
13.	2:15 PM	L. Kovanda	Review of revision draft: M27-A4
	2:45 PM	Break	

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Item	Time	Presenter	Description
14.	3:00 PM	B. Alexander	Review of revision draft: M27/M44S
15.	3:30 PM	P. Dufresne	Review of revision draft: M38-A3
16.	4:00 PM	J. Fuller	Review of revision draft: M38/51S
17.	4:30 PM	B. Alexander	Closing remarks/Adjournment

Next Meeting(s): Web Conference and/or Face-to-face: 4 June 2016, San Diego, California
Annual Meeting: 14 January 2017, Tempe, Arizona

Educational Workshop: Time 5:00 PM. – 7:00 PM
Emerging Molecular and Novel Methods to Detect Antimicrobial Resistance

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1.	Dr. Alexander opened the meeting at 9:00 AM Mountain (US) time by thanking the participants for their attendance. • A summary of the Subcommittee membership was provided. • The participants were reminded that volunteers representing pharmaceutical companies (and other ancillary organizations) are no longer allowed to participate on susceptibility testing subcommittees as voting members; therefore, because of this rule and the normal rotation schedule, the voting membership has changed radically. • The new members, advisors, and reviewers were reviewed and the members introduced themselves. • The commenting process, email voting rules, and the Chairholder's voting rules were reviewed.
2.	Mr. Glen Fine, CEO of CLSI, provided a CLSI update, including: • A brief update of changes within the CLSI governance structure and document development process • An introduction of the new CLSI staff members • An announcement about the availability of M100 free of charge on the CLSI Website in a non-downloadable format and future availability of M57S, M27/M44S, and M38/M51S in the same format once all documents publish
3.	Ms. Hackenbrack provided a detailed overview of the January 2016 CLSI governance structure and voting process. The main changes include: • Formation of the Consensus Council that acts at the consensus body (balanced representation), is responsible for project prioritization, approval of project proposals, hearing appeals, and voting to approve publication of documents. • Replacement of the Consensus Committees with Expert Panels in the 9 subject matter areas. The Expert Panels will act as the technical experts for all projects and provide recommendations to the Consensus Council and advice to Subcommittees, Document Development Committees, and Working Groups.
4.	• The minutes of the June 2015 Web conference were reviewed. There were no revisions to the minutes needed. A motion to approve the minutes was made and seconded. **VOTE: Approved (11-0).** • The rules for document review and revision was reviewed (required at 3 yrs. with yearly review through year 5 unless a revision is initiated). • A status report for each in progress document was provided. All revisions are in progress with drafts close to the final version. All drafts will be submitted for proposed draft vote as soon as M57 and M57S publish. – M27 (S. Lockhart and L. Kovanda)

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- M27/M44 (B. Alexander and A. Fothergill). Since Annette Fothergill has resigned from the subcommittee, a new volunteer to work on M27/M44S is needed.
- M38 (A. Espinel-Ingroff and P. Dufresne)
- M38/M51S (J. Fuller and M. Ghannoum)

- M57 and M57S completed proposed draft vote in November 2015 and was approved to continue in the consensus process. All comments have been addressed and reviewed and the drafts have been submitted to the editorial staff to prepare for Final Draft vote. The documents are scheduled to publish in April 2016.
- Ms. Hackenbrack noted that the title of M57S needs to be changed to distinguish it from M57. Currently, both have the same title. CLSI has change the formatting of reference citations and no longer uses the terms "Approved Guideline" or "Informational Supplement" in document titles. Therefore, using the same title for both is confusing. To be consistent with other susceptibility testing document supplements, it was agreed that the title of M57S would be revised to read, *Performance Standards for Antifungal Epidemiological Cutoff Values.*
- The status of documents not in the revision/development process were reviewed. Both M44 and M51 are not being revised but were reaffirmed in January 2015 at the 3 year mark. Both documents need to be reviewed yearly until year 5 unless the revisions are initiated.
  - Dr. Shortridge will assist Dr. Alexander with the revision of M27/M44S.
  - Dr. Procop will review M44.
  - Dr. Wiederhold will review M51.

The timelines and status of each document project is summarized below.

Activity	Document/Supplement					
	M57	**M57-S**	**M27-A4**	**M27/M44S**	**M38-A3**	**M38/M51S**
Volunteers	ECV WG	ECV WG	Lockhart Kovanda	Alexander Shortridge	Dufresne Espinel-Ingroff	Fuller Ghannoum
Working Group finalizes Draft	Done	Done	March 1, 2016	March 1, 2016	March 1, 2016	March 1, 2016
Edit final draft – 30 days	Done	Done	March	March	March	March
Submit for Review & Vote – 60 days • Antifungal SC (vote) • Micro Expert Panel (review) • Delegates (vote)	Approved	Approved	April 2016 (after M57/ M57S publish)	April 2016 (after M57/ M57S publish)	April 2016 (after M57/M57S publish)	April 2016 (after M57/ M57S publish)
Working Group Addresses Comments – 60 days	Done	Done	May/June	May/June	May/June	May/June
Final Edit -- 4-6 weeks	Dec/Jan	Dec/Jan	July	July	July	July
Final Vote (Consensus Council) – 20 days	Jan	Jan	Aug	Aug	Aug	Aug
Comment resolution	Feb	Feb	Sep	Sep	Sep	Sep

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Prepare for publication	March	March	Oct	Oct	Oct	Oct
Publication	April	April	Nov	Nov	Nov	Nov

5. The ECV Antifungal Working Group Charter and membership was reviewed. The purpose for forming the WG is to:

- Define the process for determining antifungal ECVs
- Provide transparency and support to the process
- Ensure ECVs are updated as data is available
- Revise M57S annually as needed

The ECV WG roster includes:

- Mahmoud Ghannoum (Chairholder)
- Shawn Lockhart (Vice-Chairholder)
- **Members:**
  - Philippe Dufresne
  - Ana Espinel-Ingroff
  - Jeff Fuller
  - Kerian Grande Roche
  - John Turnidge
  - Nathan Wiederhold
- **Advisor:** Mike Birch
- Additional members and/or advisors may be added to the WG. The Chairholder and Vice-chairholder will be responsible for appointing a WG secretary. **NOTE:** Mariana Castanheira and Tom Walsh have been added to the working group as an advisor and a member, respectively.

6. Dr. Lockhart reviewed the data requirements and submission form for ECV analysis.

- Dataset to include data from:
  - 3 laboratories minimum
  - No single laboratory providing more than 50% of data
  - 100 unique isolates
  - Data set must be generated using the reference broth microdilution method as outlined in M27 for yeasts and M38 for moulds
  - Tested isolates should be identified with molecular methods (refer to MM18 for preferred targets for identification). Whether a species is required or a species complex is acceptable needs to be determined on a case by case basis.
- ECV will be determined by iterative statistical method (ECOFFinder Excel Spreadsheet Calculator (posted on CLSI website with detailed instructions)
- ECV = 24 hour MIC/MEC that captures 97.5% of the modeled wild-type (WT) distribution
- ECV WG to review new data and provide quarterly updates
- A process to be used by the ECV WG to qualify submitted data will be created.

It was suggested that the submission form be revised to include QC and solvent information.

- Guidelines will be drafted around assurance of data quality.
- A standardized format for the analyzed data was reviewed.

The plan for the ECV data repository was discussed.

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Submitted raw data not reviewed by the ECV working group will be stored in a designated folder on the ECV WG page in Workspace. The unreviewed data will be accessible by the WG. The data's origins will be available to the WG, but will be kept anonymous to all others. The working group will meet on a quarterly basis to review all raw data.
ECV data that is deemed acceptable by the WG will be anonymized, analyzed, and presented in a standardized format for review and/or vote by the full subcommittee. This data will be posted on the AFSC page in Workspace.

The plan for using and sharing analyzed ECV data was reviewed and discussed.

The participants agreed that:

ECVs will be published in M57S. The data will be retained for review and revision of established ECVs when new data become available
Raw data will be posted under Documents on the restricted ECV WG page in Workspace
Clean, anonymized data will be posted under Documents on the Antifungal SC page in Workspace

The following issues need to be discussed and a plan developed by the ECV WG

Will the SC publish the ECV data outside of M57S? The general consensus was “yes”. If so, how will authorship for the publications be decided? In general, authorship would be determined independently for each project and would follow standard guidelines used by journals and would warrant authors participation in the research including data analysis. Those who contributed data would also be recognized. A formal plan for this will be developed using the AIDS Clinical Trials Group author agreement as a template.
Are there laws for protecting posted data? The CLSI legal team will be consulted for copyright jurisdiction. Glen Fine will investigate CLSI ownership and protection of data.
Will raw anonymized data be shares with third parties such as EUCAST? The general consensus was “yes”.
Will raw anonymized data be shared with other third party researchers? The general consensus was “yes”.
How will this be decided? Data sharing with third parties would be decided on a case by case basis with ultimate decision made by the Chairholder, Vice-Chairholder of ECV working group and the Antifungal Subcommittee Chairholder. A formal plan for this will be developed.

The ECV WG will develop a set of criteria and formalize a plan for sharing data to be reviewed and discussed by the full subcommittee on the June 2016 Web conference.

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The participants reviewed the current ECVs (to be published in M57S) and discussed what ECVs are still needed. The ECVs still needed include those in the lists below.
<table>
<tr><th>Drug</th><th>Organism (Yeasts)</th><th>Issue</th></tr>
<tr><td>Itraconazole</td><td>C. albicans
C. parapsilosis</td><td>• Modes were spread across a wide range; several laboratories truncated at lower end; need more data</td></tr>
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Flucytosine	*Candida* species	• Majority of labs had truncated data for all species resulting in only 2 to 3 labs contributing data for *C. albicans, C. glabrata,* and *C. parapsilosis* and with 1 lab contributing >50% of data. • *C. tropicalis & C. krusei* weighted analyses resulted in ECVs one dilution higher than unweighted; need more data
Voriconazole	*C. glabrata*	• No ECVs for any *Candida* species; data available
Posaconazole	*Candida* species	• No ECVs for any *Candida* species; data available
Isavuconazole	*Candida* species	• No ECVs for any *Candida* species; data from one lab only
All drugs	*Cryptococcus* species	• Data available for fluc, itra, posa, vori, isavu, ampho, 5FC

Drug	Organism (Moulds)	Issue
Posaconazole	*Aspergillus fumigatus*	• Proposed ECV (0.5) may be too high based on data presented by Dr. Meis. Dr. Meis and Dr. Dufresne to provide data (for isolates with and without mutations) for re-analysis
All drugs	*Aspergillus nidulans*	• Tri-modal MIC distribution suggesting need for molecular identification of isolates; need more data
All drugs	Mucorales	• Data available for *L. corymbifera*, *M. circinelloides*, *R. arrhizus, R. microspores* and ampho, itra, posa
All drugs	*Fusarium* spp.	• Data available for *F. verticillioides*, *F. oxysporum*, *F. solani* and ampho, itra, posa, vori

- Additional data is needed for the following:
  - Flucytosine: It was noted that the panels need to be re-formulated; however, the drug is not readily available.
  - Isavuconazole: Data for *Candida* spp. are needed. Dr. Espinel-Ingroff, Ms. Kovanda, and Dr. Ghannoum will provide data.
  - Mucorales and *Fusarium*: Dr. Espinel-Ingroff will be asked to provide data.

8. Dr. Lockhart presented an update on the status of ECVs for *Cryptococcus* spp.
- Data and proposed ECVs for *Cryptococcus* and several antifungal agents has been published (see below).
- The raw data has not yet been submitted to the ECV working group for review. Before the ECVs can be voted on with the intent to publish in the next edition of M57S, it needs to be reviewed, cleaned, re-analyzed, and presented to the full subcommittee for vote.
- It is expected that the *Cryptococcus* ECVs will be available for review and vote during the summer Web conference.

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- A note regarding nomenclature changes will also be included in the M57S revision.

Organism	Antifungal Agent	ECV in µg/mL
C. neoformans VNI (*C. neoformans*)	Amphotericin B	0.5
	Flucytosine	8
	Fluconazole	8
	Voriconazole	0.25
	Itraconazole	0.5
	Posaconazole	0.25

Organism	Antifungal Agent	ECV in µg/mL
C. gattii VGI (*C. gattii*)	Amphotericin B	0.5
	Flucytosine	4
	Fluconazole	16
	Voriconazole	0.5
	Itraconazole	0.5
	Posaconazole	0.5

Organism	Antifungal Agent	ECV in µg/mL
C. gattii VGII (*C. deuterogattii*)	Amphotericin B	1
	Flucytosine	16
	Fluconazole	16
	Voriconazole	0.5
	Itraconazole	1

9. Dr. Lockhart presented an update on the status of ECVs for *Candida* spp. and the azoles.

- Data and proposed ECVs for *Candida* spp. *and* azoles has been published (see below).
- The raw data obtained by Dr. Espinel-Ingroff has not yet been submitted to the ECV working group for review. Before the ECVs can be voted on with the intent to publish in the next edition of M57S, it needs to be reviewed, cleaned, re-analyzed, and presented to the full subcommittee for vote.
- It is expected that the *Candida* ECVs for the azoles will be available for review and vote during the summer Web conference.

Antifungal agent	Species	No. of isolates/no. of labs	MIC (range) (µg/mL)	Mode (µg/mL)	ECV (µg/mL) at the indicated % of the modeled WT population	
					95	97.5
Fluconazole	*C. albicans*	5,265/9	0.06 to ≥128	0.12	0.5	0.5
	C. dubliniensis	162/7	0.06 to 64	0.25	0.5	0.5
	C. glabrata	7,538/14	0.12 to ≥128	4	8	8
	C. guilliermondii	373/11	0.12 to 64	2	8	8
	C. krusei	1,073/11	0.25 to ≥128	16	32	32

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		C. lusitaniae	574/10	0.12 to 64	0.5	1	1
		C. parapsilosis	6,023/15	0.06 to ≥128	0.5	1	1
		C. tropicalis	3,748/14	0.06 to ≥128	0.25	1	1
	Posaconazole	*C. albicans*	11,241/9	0.008 to ≥8	0.016	0.06	0.06
		C. dubliniensis	151/7	0.008 to 0.5	0.03	0.25	0.25
		C. glabrata	2,131/7	0.008 to ≥8	0.25	1	2
		C. guilliermondii	298/6	0.008 to 2	0.12	0.5	0.5
		C. krusei	872/10	0.016 to 4	0.25	0.5	0.5
		C. lusitaniae	521/7	0.008 to 1	0.016	0.06	0.06
		C. parapsilosis	3,451/7	0.008 to 2	0.03	0.25	0.25
		C. tropicalis	2,613/8	0.008 to ≥8	0.03	0.12	0.12
	Voriconazole	*C. albicans*	3,210/9	0.008 to ≥8	0.016	0.03	0.03
		C. dubliniensis	152/7	0.008 to 1	0.016	0.03	0.03
		C. glabrata	4,176/11	0.008 to ≥8	0.06	0.25	0.25
		C. guilliermondii	369/12	0.008 to ≥8	0.03	0.12	0.12
		C. krusei	930/12	0.008 to 2	0.12	0.25	0.5
		C. lusitaniae	142/8	0.008 to 0.25	0.016	0.06	0.06
		C. parapsilosis	2,337/8	0.008 to 2	0.016	0.03	0.03
		C. tropicalis	3,127/8	0.008 to ≥8	0.016	0.06	0.12

10. Dr. Ghannoum reviewed the plans for educating laboratories and clinicians on the use of ECVs. Ideas for providing education included:

- Presenting information at scientific meetings such as ASM/ICAAC and ID week.
- Publishing a mini-review in the Journal of Clinical Microbiology.
- Working with the AST outreach group (co-chaired by Audrey Schuetz) to include information in an Outreach Newsletter, schedule a Webinar, and post information in ClinMicroNet. It was suggested that PACE or CME credits might be offered for attending the Webinars. It was also suggested that ClinMicroNet could also be a means to advertise for ECV data.
- Dr. Ostrosky-Zeichner will contact the Mycoses Study Group (Terranova) to assess interest in developing a CE accredited program summarizing ECVs and their use for clinicians.

It was also noted that M57 provides examples of language for ECVs reports that provide guidance to clinicians on the differences between breakpoints and ECVs.

11. Dr. Alexander reviewed the next steps for revising M57S to M57S2 (2nd edition).

- Missing data will be gathered.
  - **Itraconazole for *C. albicans* and *C. parapsilosis***: Modes were spread across a wide range with several laboratories truncated at the lower end.
  - **Flucytosine and *Candida* spp**.: Truncated data at the lower end for most laboratories
  - **Azoles and *A. nidulans*** ECVs: Trimodal MIC distribution and molecularly typed strains needed.

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	– **Posaconazole and A fumigatus:** ECV of 0.5 is too high, majority of isolates with TR34 & TR46 mutations had MIC=0.5; only 2/178 WT isolates had MIC 0.5 (mode 0.063). – **Isavuconazole and *Candida* spp.**: Need data from laboratories other than JMI. • Reanalyze raw data and vote on new ECVs – Voriconazole, posaconazole and fluconazole and Candida spp. – All drugs and Mucorales (amphotericin B, itraconazole, posaconazole and *L. corymbifera*, *M. circinelloides*, *R. arrhizus*, *R. microspores*) – All drugs and *Fusarium* spp. (amphotericin B, itraconazole, posaconazole, and voriconazole with *F. verticillioides*, *F. oxysproum*, *F. solani*)
12.	Dr. Perlin provided an update from the Caspofungin Working Group. • CLSI established drug and species specific breakpoints for all echinocandins that captured prominent FKS resistance mechanism. But inter-laboratory testing variability observed with CSF renders the CSF breakpoint unreliable. • Factors influencing caspofungin testing include methodological factors (coated vs uncoated plates, in adequate QC strains. No methodological change or new QC strain has been identified that corrects the problem with testing. • Considerations for dealing with the issue include the following: – Since micafungin and anidulafungin are reliable markers for susceptibility based on FKS status, these could be used as testing surrogates – Recommend molecular genotyping of *Candida* strains as the most direct means to confirm resistance-associated mutations in FKS genes • Discussion on the two options included: – It was noted that there are no issues with the other echinocandins so it can be assumed that there is no procedural issue except for drug stock or dilution preparation. Also, just because two drugs are working well doesn't imply that the procedure is being performed correctly. – It was agreed that there may be multiple factors that are contributing to the variability. Also, even when the result tests as resistant, treatments may still be effective. It was agreed that the issue only seems to be an *in vitro* phenomenon. – It was noted that when caspofungin tests as "susceptible", the result is reliable but that "intermediate" and "resistant" results should be confirmed. • A motion to add language to M27/M44S for broth dilution testing that would recommend reflex testing to confirm resistance was made and seconded. **VOTE: Approved (9 approve; 1 reject; 1 absent).** • The language was edited by the participants. The following language was approved to be added to M27/M44S for broth dilution testing: **"Caspofungin susceptibility testing *in vitro* has been associated with significant interlaboratory variability contributing to reports of false resistance when using the M27 reference method.[2] The cause of the variability is unclear. When testing caspofungin, susceptible results may be reported as susceptible; however, laboratories should confirm intermediate or resistant results by either: a) further susceptibility testing with micafungin[3] or anidulafungin[4] or b) DNA sequence analysis of *FKS* genes to identify resistance hot spot mutations in *FKS1* (all *Candida* species) and *FKS2* (*C. glabrata* only) [Reference?] or c) sending to a referral laboratory for confirmation. *Candida* spp. resistant to anidulafungin or micafungin or possessing characteristic *FKS* hot spot mutations are**

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	considered resistant to all echinocandins including caspofungin and should be reported as such." **References** 2. Espinel-Ingroff A et al. Interlaboratory variability of caspofunign MICS for *Candida* spp. Using CLSI and EUCAST Methods: Should the clinical laboratory be testing this agent? *AAC* 2103:57(12):5836-5842. 3. Pfaller MA, Messer SA, Diekema DJ, Jones RN, Castanheira M. Use of micafungin as a surrogate marker to predict susceptibility and resistance to caspofungin among 3,764 clinical isolates of *Candida* by use of CLSI methods and interpretive criteria. *J Clin Micro*. 2014;52(1): 108-114 4. Pfaller MA, Diekema DJ, Jones RN, Castanheira M. Use of anidulafungin as a surrogate marker to predict susceptibility and resistance to caspofungin among 4,290 clinical isolates of *Candida* by using CLSI methods and interpretive criteria. *J Clin Micro*. 2014;52(9):3223-3229 Dr. Perlin will provide the missing reference.
13.	Ms. Kovanda reviewed the current draft of M27 (4th ed). • Reading QC results at 24 and 48 hrs. was discussed. It was questioned as to whether 48 hr. QC readings are needed. – M27 states to read yeasts at 24 hr except *Cryptococcus* which is read at 72 hrs. – If there is insufficient growth with patient isolates, they can be read at 48 hrs; however, QC should be read only at 24 hrs. – A motion was made and seconded to recommend reading and reporting QC at 24 hrs. For patient isolates, results should be read at 24 hrs and at 48 hrs if there is insufficient growth with no need to hold the QC. **VOTE: Approved (11 – 0)** • Ms. Kovanda and Dr. Lockhart will continue to review and address any questions in preparation for proposed draft vote after M57 and M57S publish.
14.	Dr. Alexander reviewed the current draft of M27/M44S (1st ed). A volunteer to assist Dr. Alexander will be recruited. • For consistency with other CLSI susceptibility testing documents, the title will be revised to read, "*Performance Standards for Antifungal Susceptibility Testing of Yeasts*". • The language in the Foreword regarding use of CLSI or FDA breakpoints will be retained for the time being. A new CLSI board policy may require that the language be revised as it may appear to be too US-centric. • The footnote regarding caspofungin testing in Table 1 will be revised as discussed in agenda Item 12. Dr. Perlin will provide a reference for the footnote. • Note 2 for Table 2 will emphasize that there are no breakpoints for itraconazole with *Candida* spp. • In Table 5, the columns for 48 hr QC readings will be deleted. • For those using a commercial test system, a note recommending that laboratories follow the manufacturer's QC will be added. This comment from M100 will be used as a guide: "When a commercial test system is used for susceptibility testing, refer to the manufacturer's instructions for QC test recommendations and QC ranges." • In Table 6, the footnote about reading breakpoints at 48 hrs was deleted. • The ranges for *C. glabrata* will be revisited and may be adjusted. Dr. Brown and Ms. Kovanda will review the

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	original Clinical Microbiology Institute data. The data will be reviewed at the next subcommittee meeting. • Dr. Alexander will continue to review and address any questions in preparation for proposed draft vote after M57 and M57S publish.
15.	Dr. Dufresne reviewed the current draft of M38 (3rd ed). • It was suggested that a table with fungal nomenclature and molecular markers be added. It was decided that this suggestion will be revisited. • Chapter 2 (Indications for Performing Susceptibility Testing) will be revised to be more specific for moulds. The triggers for mould susceptibility testing will be emphasized. • Subchapter 3.2.4.1 (Nondermatophyte Moulds) – The echinocandin ranges will be adjusted. – Flucytosine and fluconazole may be deleted. – Terbinafine may be added • Subchapter 3.2.4.2 (Dermatophyte Moulds): The upper limit of the testing range for terbinafine will be increased to 2.0 µg/mL. • It was noted that M38 and M27 need to be harmonized. • Dr. Dufresne and Dr. Espinel-Ingroff will continue to review and address any questions in preparation for proposed draft vote after M57 and M57S publish.
16.	Dr. Fuller reviewed the current draft of M38/M51S (1st ed). • The Foreword will be harmonized with M38. • The revision of Table 1 is in progress. The incubation times for the yeast QC organisms will be checked so that they are read at 24 hrs.
17.	Dr. Alexander reviewed the action items from the meeting and designated responsible parties and due dates (see table below). She thanked the attendees for their hard work and participation. The meeting was adjourned at 4:00 PM Mountain (US) time.
	Next meetings: Web Conference Spring/Summer 2016 14 January 2017, Tempe, Arizona (Mission Palms) It was agreed that the subcommittee will meet by Web conference in the summer of 2016. A poll for availability will be distributed.

ACTION ITEMS

No.	Description	Responsibility	Due Date
1.	Select Secretary of the ECV working group	M. Ghannoum S. Lockhart	2/9/16
2.	Update ECV Repository Data Sharing Plan	S. Lockhart	2/9/16
3.	Collect additional data for *A. nidulans* with all drugs.	P. Dufresne	June 2016
4.	Draft a blast email requesting susceptibility testing data for specific organisms (eg, A. nidulans) for distribution through ClinMicroNet.	S. Lockhart	2/9/16

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No.	**Description**	**Responsibility**	**Due Date**
5.	Reanalyze posaconazole data for *A. fumigatus* (including data from Dr. Meis)/(Draft a note for footnote if can't separate)	P. Dufresne	June 2016
6.	Submit raw *Candida* data (fluconazole, voriconazole, posaconazole) to ECV Working Group / Data Repository	A. Espinel-Ingroff	3/9/16
7.	Review raw data for ECVs for *Candida* and fluconazole, voriconazole and posaconazole and perform analysis if needed.	ECV WG	June 2016
8.	Vote on ECVs for *Candida* and fluconazole, voriconazole and posaconazole	SC members	June 2016
9.	Submit raw *Cryptococcus* data to ECV Working Group / Data Repository	A. Espinel-Ingroff	2/9/16
10.	Complete re-analysis of Crypto ECVs for amphotericin B, flucytosine, fluconazole, voriconazole, itraconazole, and posaconazole for SC review	ECV WG	June 2016
11.	Vote on *Cryptococcus* ECVs for amphotericin B, flucytosine, fluconazole, voriconazole, itraconazole, and posaconazole for SC review	SC members	June 2016
12.	Submit raw F*usarium* data to ECV Working Group / Data Repository	A. Espinel-Ingroff	4/9/16
13.	Re-analyze *Fusarium* ECV data for amphotericin B, itraconazole, posaconazole, and voriconazole for SC review	ECV WG	June
14.	Submit raw Mucorales data to ECV Working Group / Data Repository	A. Espinel-Ingroff	5/9/16
15.	Re-analyze Mucorales data for amphotericin B, posaconazole, and itraconazole	ECV WG	June
16.	Perform Annual Review M51	N. Weiderhold	June 2016
17.	Perform Annual Review M44	G. Procop	June 2016
18.	Finalize Draft M27 revision	Lockhart Kovanda	3/1/16
19.	Finalize Draft M27/M44S	Alexander Shortridge	3/1/16
20.	Finalize Draft M38 revision	Dufresne Espinel-Ingroff	3/1/16
21.	Finalize Draft M38/M51S	Fuller Ghannoum	3/1/16
22.	Request & review data for zone interpretive criteria for *C. glabrata* and anidulafungin and micafungin, from Dr. Arendrup and Dr. Brown (CMI).	S. Brown	June 2016
23.	Revisit data for *C. glabrata* with voriconazole	D. Perlin	June 2016
24.	Submit raw Candida / isavuconazole data to ECV Working Group/ Data Repository for analysis	Laura Kovanda	3/9/16