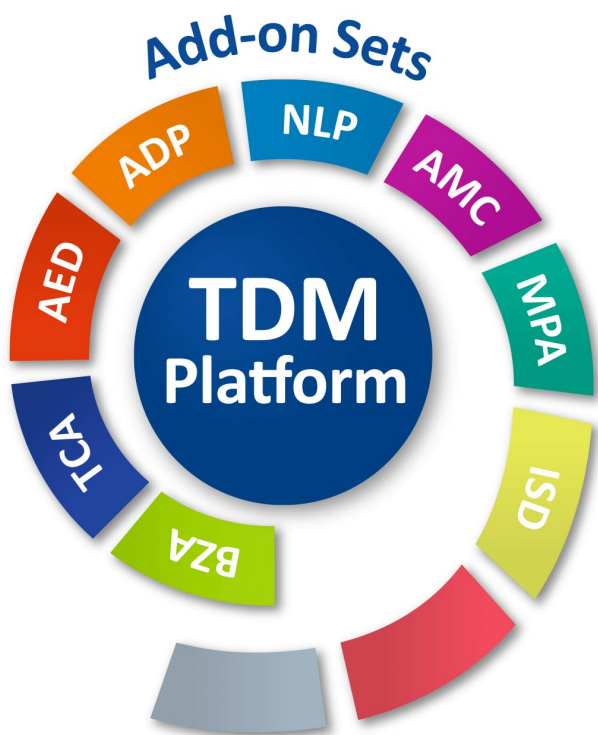


Antimycotics in serum/plasma



Antimycotics

The "ClinMass® TDM Kit System" is based on a universal TDM Platform (order no. MS9000), which can be used with various Add-on Sets for the Therapeutic Drug Monitoring (TDM).

The ClinMass® Add-on Set for Antimycotics (order no. MS9600) is intended for the determination of Antimycotics from human serum or plasma.

- + avoiding antifungal drug-resistance
- + identification of target through concentration

Therapeutic Drug Monitoring (TDM)

Increasing recommendation in

- + conditions with a small therapeutic range
- + optimisation of a personalised pharmacotherapy
- + monitoring the effective therapy regime
- + detection of drug/drug interactions
- + toxicity avoidance
- + monitoring of patient's compliance

Please note:

The use of the RECIPE Kit System requires an LC system with tandem mass spectrometer (LC-MS/MS) with sufficient sensitivity and evaluation software.



Clinical Background

Invasive fungal infections, predominantly aspergillosis and candidiasis, are the most important causes of morbidity and mortality in immunocompromised patients. Primarily, patients with acute leukemia undergoing myelosuppressive chemo-therapy and allogeneic stem cell trans-plant recipients are affected. Up to 60 % of patients with invasive aspergillosis, the most common invasive mycosis among patients with hematologic malignancies, may still die of their infection, once it has become clinically overt .

Antimycotics (antifungal drugs, anti-fungals) are a class of drugs that are used for the treatment and prophylaxis of fungal infections.

Therapeutic drug monitoring (TDM) is the clinical laboratory practice to determine drug concentrations in blood to optimise a personalised pharmacotherapy, especially in indications with a small therapeutic range. Drug interactions, efficacy, toxicity avoidance and the surveillance of compliance are typical indications where TDM is requested.

The RECIPE analytical method provides the reliable quantification of 11 antimycotics.

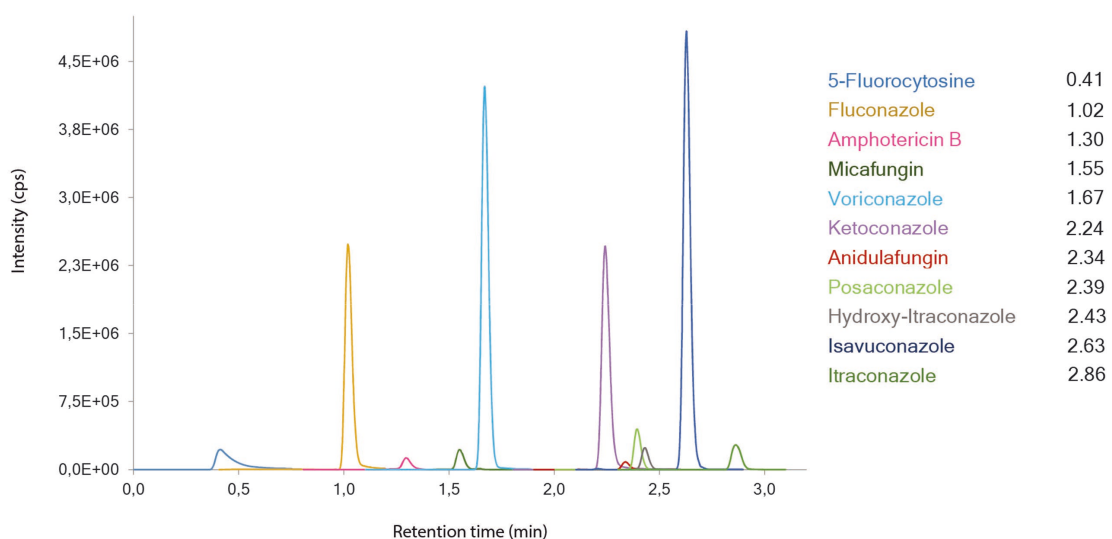


Figure 1 Chromatogram of the ClinCal® Serum Calibrator (order no. MS9613), level 2



Method Performance

The interassay precision of the method was determined with samples at two concentration levels. The samples were prepared by different persons on eight different days and measured on several systems from different manufacturers (for data from a specific system please contact info@recipe.de). The analyte concentrations were selected according to the respective therapeutic reference range and are contained in Table 2 together with the precision results.

Analyte	Concentration [mg/l]		Intraassay Precision [%] (mean value)		Interassay Precision [%]	
	Level		Level		Level	
	I	II	I	II	I	II
5-Fluorocytosine	11.3	75.0	2.8	3.4	5.1	2.8
Amphotericin B	0.750	5.0	2.8	6.4	9.3	6.8
Anidulafungin	1.50	10.0	11.4	8.2	13.4	11.1
Fluconazole	1.50	10.0	4.7	3.0	4.0	3.2
Isavuconazole	1.50	10.0	7.5	4.9	5.6	1.8
Itraconazole	0.450	3.00	7.9	4.8	7.3	2.7
Ketoconazole	1.50	10.0	7.9	3.8	5.0	4.8
Micafungin	6.00	40.0	9.0	11.4	13.0	8.6
Hydroxy-Itraconazole	0.600	4.00	7.3	3.8	7.1	6.1
Posaconazole	0.750	5.00	7.6	4.7	6.9	4.7
Voriconazole	0.750	5.00	6.0	2.7	3.6	2.5

Table 2. Method Performance/Precision data



The following ranges are taken from the data collection according to Schulz et al.

Analyte	Therapeutic Range [mg/l]*
5-Fluorocytosine	35–70 (20–50)
Amphotericin B	(0.1) 0.2–3.0
Anidulafungin	n.a.
Fluconazole	appr. 1–5 (–15)
Isavuconazole	n.a.
Itraconazole	appr. 0.4–2
Ketoconazole	1–3 (–6)
Micafungin	n.a.
Hydroxy-Itraconazole	n.a.
Posaconazole	> 0.7 (for invasive aspergillosis)
Voriconazole	2–6

*Note:

e.g. 35–70 (20–50) means: Mainly a range between 35–70 mg/l is indicated, in some publications however a range between 20–50 mg/l

n.a.: not available



Conclusion

The RECIPE 200 TDM Kit

- ✓ improves the individual therapeutic regimen for the patient
- ✓ adopts fast growing medical need by regular addition of new drug classes
- ✓ is validated, no new validation is necessary
- ✓ offers you a flexible expansion of the add-on sets



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