



Translation of AOO-ISS – 30/08/2022 –  
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**Subject:** Measures preventing the transmission of the Monkeypox virus (MPXV) infection through fecal microbiota transplant (FMT).

In relation to the spreading, at the national and international level, of human cases of Monkeypox (MPX) and to the reports of the European Centre for Disease Prevention and Control (ECDC)<sup>1</sup>, the FDA<sup>2</sup>, the Notify Library<sup>3</sup> and to what is indicated in the internal regulations of the General Directorate for Health Prevention of the Ministry of Health of 25/5/2022 (Prot. DGPREV 0026837)<sup>4</sup>, and of 02/08/2022 (Prot. DGPREV 0034905)<sup>5</sup>, and of CNT's note of 07/06/2022 (Prot. ISS 0021745)<sup>6</sup>, although no MPXV transmission via feces or from asymptomatic infected individuals is known, the following is recommended:

- strengthen the anamnestic evaluation of the donor by finding whether in the previous 21 days MPXV positivity has been detected, symptoms and signs compatible with MPXV infection have appeared, or close contact with infected or suspected cases is reported<sup>4,5,6</sup>;
- in the presence of symptoms and signs compatible with MPXV infection, it is necessary to conduct diagnostic investigations to rule out the presence of the virus (Real Time-PCR on a swab of a vesicle after its opening)<sup>4,5,6</sup>;
- apply the 21-day temporary suspension criterion, from the last day of exposure, for donors with a history of close contact with confirmed or suspected or probable cases of MPX, or in case of recent trips to areas affected by confirmed indigenous cases of MPX or in MPX endemic countries;
- given that the prodromal stage of MPX varies in duration (1–4 days) and symptoms may be non-specific and mild or absent, perform a careful examination for any signs of infection even after the deferral period expiration date (at least 21 days from the last exposure). The examination should not overlook mild and non-specific signs such as headache or fatigue or anogenital skin lesions;
- in case of MPXV infection, FMT donation can be performed after 21 days from diagnosis and in the absence of symptoms;

<sup>1</sup>European Centre for Disease Prevention and Control - Monkeypox multi-country outbreak, 23<sup>rd</sup> May 2022 and following update of 8th July 2022.

<sup>2</sup>U.S: Food and drug Administration, [Safety Alert Regarding Use of Fecal Microbiota for Transplantation and Additional Safety Protections Pertaining to Monkeypox Virus](#), August 22, 2022.

<sup>3</sup>Monkeypox and MPXV safety The Notify MPXV safety group - position statement, July 26, 2022. [https://www.notifylibrary.org/sites/default/files/NOTIFY%20-%20MPXV\\_July26.pdf](https://www.notifylibrary.org/sites/default/files/NOTIFY%20-%20MPXV_July26.pdf) (last access 29.08.2022)

<sup>4</sup> Internal regulations of the General Directorate for Health Prevention of the Ministry of Health of 25/5/2022

<sup>5</sup> Internal regulations of the General Directorate for Health Prevention of the Ministry of Health of 02/08/2022 (Prot. DGPREV 0034905)

<sup>6</sup>Note of the Italian National Transplant Centre of 07/06/2022 (Prot. ISS 0021745)



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- prior to the use of the product, it will be necessary to repeat the donor assessment, to evaluate the appearance of symptoms compatible with MPXV infection in the 21 days after donation (post donation information). The donor evaluation must be carried out retrospectively for the use of FMT prepared from fecal material donated from March 15, 2022. In case of MPXV positivity or of appearance of symptoms, the donor must be considered unsuitable and the Italian National Transplant Center must be notified.