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Bifidobacterium animalis subsp. lactis

Change to read:

DEFINITION

▲ *Bifidobacterium animalis* subsp. *lactis* is a lactic-acid producing, Gram-positive, rod-shaped, non-spore-forming, anaerobic bacterium that is pleomorphic. Various rod shapes may be observed, but they are typically curved or clubbed and often branched. Suitable cryoprotectants may be added to the concentrated bacteria following fermentation, after which the product is frozen or freeze-dried. The formulated product may be blended with suitable diluents and/or bulking agents. It contains NLT 100% of the labeled viable cell count of the specified strain of *Bifidobacterium animalis* subsp. *lactis*.

- **Strain Bi-07:** *Bifidobacterium animalis* subsp. *lactis* Bi-07 (ATCC SD 5220) is a pure, specific strain of *Bifidobacterium animalis* subsp. *lactis*.
- **Strain BI-04:** *Bifidobacterium animalis* subsp. *lactis* BI-04 (ATCC SD 5219) is a pure, specific strain of *Bifidobacterium animalis* subsp. *lactis*.
- **Strain HN019:** *Bifidobacterium animalis* subsp. *lactis* HN019 (ATCC SD 5674) is a pure, specific strain of *Bifidobacterium animalis* subsp. *lactis*.
- **Strain B420:** *Bifidobacterium animalis* subsp. *lactis* B420 (ATCC SD 6685) is a pure, specific strain of *Bifidobacterium animalis* subsp. *lactis*.

[NOTE—The nucleic acid-based method detailed in *Identification B* applies only to *Bifidobacterium animalis* subsp. *lactis* Bi-07, BI-04, HN019, and B420.]▲ (USP 1-May-2023)

IDENTIFICATION

Add the following:

▲ **A. MICROSCOPIC IDENTIFICATION**

Analysis: Proceed as directed in the Assay and perform microscopic examination.
Acceptance criteria: Rod-shaped bacterium. Various rod shapes may be observed, but they are typically curved or clubbed and are often branched.▲ (USP 1-May-2023)

Change to read:

- ▲ **B.▲ (USP 1-May-2023) NUCLEIC ACID-BASED IDENTIFICATION**
▲▲ (USP 1-May-2023)

Buffer: Use a molecular biology-grade ▲ [tris-EDTA buffer, pH 8.0 TS](#).▲ (USP 1-May-2023)
Sample solution: 100 mg/mL of the freeze-dried probiotic powder in *Buffer*
Primer sets: ▲ See [Table 1](#).▲ (USP 1-May-2023)

Table 1. Primer Sets and Acceptance Criteria

Strain	Primer Set ^a	Primer Sequence	Acceptance Criteria ^b
Bi-07	1	Forward (5'-3') CATCGCAACTTCACCCACATTG and Reverse (5'-3') ATGCCGTACCCCTGAATGAAG	An amplification product of 533 base pairs. There should be no amplification product of 479 base pairs.
	2	Forward (5'-3') ACGGATATGTATAGGTGGCATG C and Reverse (5'-3') GTATGTTCAATCGTATGCAGCC C	An amplification product of 492 base pairs with 1 single-nucleotide polymorphism (SNP). The SNP sequence is identified as (underlined in the following 15 base-pair



Strain	Primer Set ^a	Primer Sequence	Acceptance Criteria ^b
			sequence) GCGGGCA ^a GTGCTGG, and the location is 218 base pairs from the 5' end of the forward primer. The sequence of the amplicon should be determined by validated, standard sequencing technologies, [▲] like Sanger sequencing. [▲] (USP 1-May-2023)
BI-04	1	Forward (5'-3') CATCGCAACTTCACCCACATTG and Reverse (5'-3') ATGCCGTACCCCTGAATGAAG	An amplification product of 479 base pairs. There should be no amplification product of 533 base pairs.
HN019	1	Forward (5'-3') ACTCTTCTGTGTCGTTCTGCTT C and Reverse (5'-3') CAAGGATTGGAACGCGAGAAA AC	An amplification product of 351 base pairs with 1 SNP. The SNP sequence is identified as (underlined in the following 15 base pair sequence) CTTCAG ^a TTTTAGGC, and the location is 44 base pairs from the 5' end of the forward primer. The sequence of the amplicon should be determined by validated, standard sequencing technologies [▲] like Sanger sequencing. [▲] (USP 1-May-2023)
	2	Forward (5'-3') CCTGCTGTGGTGAATACGAAG AA and Reverse (5'-3') TTGCATCTTGACAGTTCGGCA T	An amplification product of 531 base pairs with 1 single-nucleotide polymorphism (SNP). The SNP sequence is identified as (underlined in the following 15 base pair sequence) GCCCGC ^a CAAACGAA and the location is [▲] 278 [▲] (USP 1-May-2023) base pairs from the 5' end of the forward primer described in primer set 2. The sequence of the amplicon should be determined by validated, standard sequencing technologies [▲] like Sanger sequencing. [▲] (USP 1-May-2023)
[▲] B420	1	Forward (5'-3') CCTGCATGGGGAATCGTGTA and Reverse (5'-3') TCCTAGAATGCTTGTGTTTGC G	An amplification product of 231 base pairs with 1 single-nucleotide polymorphism (SNP). The SNP sequence is identified as (underlined in the following 11 base pair sequence) TGAAG ^a CCCTTT and the location is 171 base pairs