

Cytori® Celase® GMP or SERVA Collagenase NB?

Cytori Celase GMP is a blended proteolytic enzyme designed for *in vitro* dissociation of adipose tissue from a variety of species. Celase GMP is a mixture of highly purified collagenase and neutral protease enzymes, formulated for efficient, gentle, and reproducible dissociation of adipose cells from their surrounding tissue matrix. The target substrates for Celase GMP are the collagen and non-collagen proteins that comprise extracellular matrix and bind cells into a three-dimensional tissue. Celase GMP is aseptically processed, sterile filtered, and highly purified to assure the lowest levels of impurities. Celase GMP is provided as a single-use unit consisting of a clear glass vial within a foam-protected canister.

Collagenase Activity Per mg of Enzyme

EnzChek Gelatinase Assay Kit is a commercially available kit that provides a rapid and highly sensitive method to measure collagenase/gelatinase activities. The fluorescent intensity correlates strongly with collagenase activity¹. Based on the side-by-side collagenase activities measured by this kit, the collagenase activity per mg for the Cytori Celase GMP was on average 6 times higher than that for the SERVA Collagenase NB 4 (Figure 1).

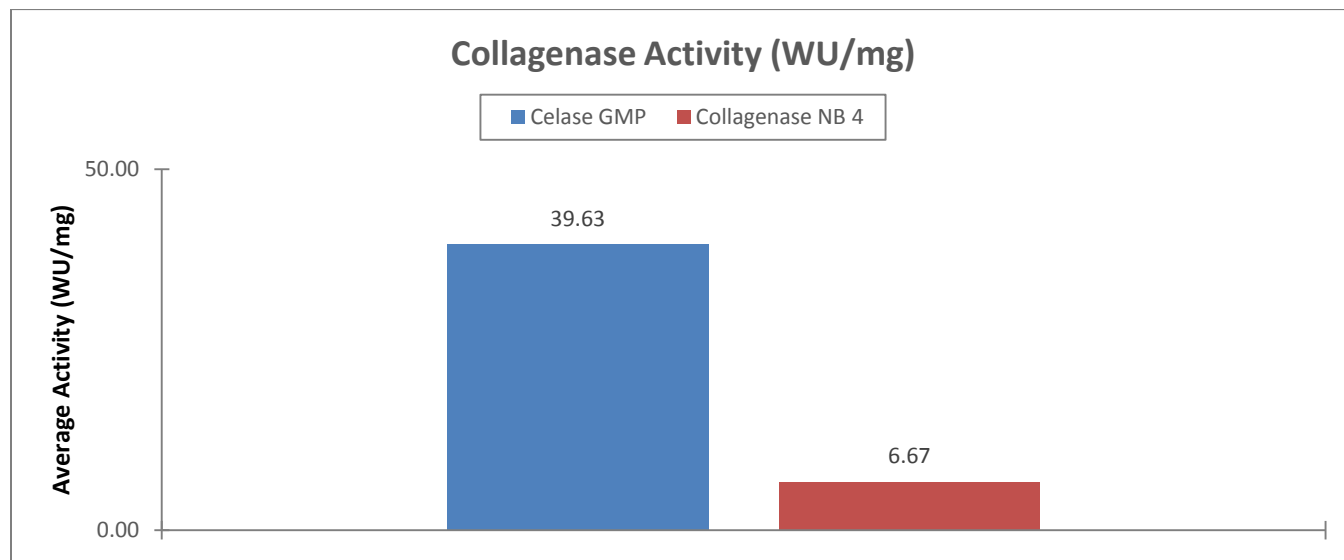


Figure 1. Side-by-side comparison of collagenase activity measured using the EnzChek Gelatinase Assay Kit (n=2). The specific activity of Celase GMP (enzyme activity per mg of enzyme) was, on average, 6 times higher than that of the Collagenase NB 4 enzyme. Data on file.

Digestion Performance Comparison

Digestion is the process by which a collagenase enzyme dissociates extracellular matrix and releases tissue cells². The ability of Celase GMP and Collagenase NB 6 GMP enzymes to release cells from the adipose tissue of three human donors was examined:

- Using human lipoaspirate as the substrate,
- Adjusting the collagenase concentration of both enzymes to 1 WU/mL,
- Maintaining a digestion temperature of 37°C,
- Fixing the digestion processing solution volume and digestion time (20 minutes), and
- Each run used the same donor tissue; three donors evaluated.

The yield of viable nucleated cells per gram of tissue using Celase GMP was, on average, 3.0 times higher than that using Collagenase NB 4 enzyme (Figure 2). Cell viability was comparable with an average of 90% for both enzymes.

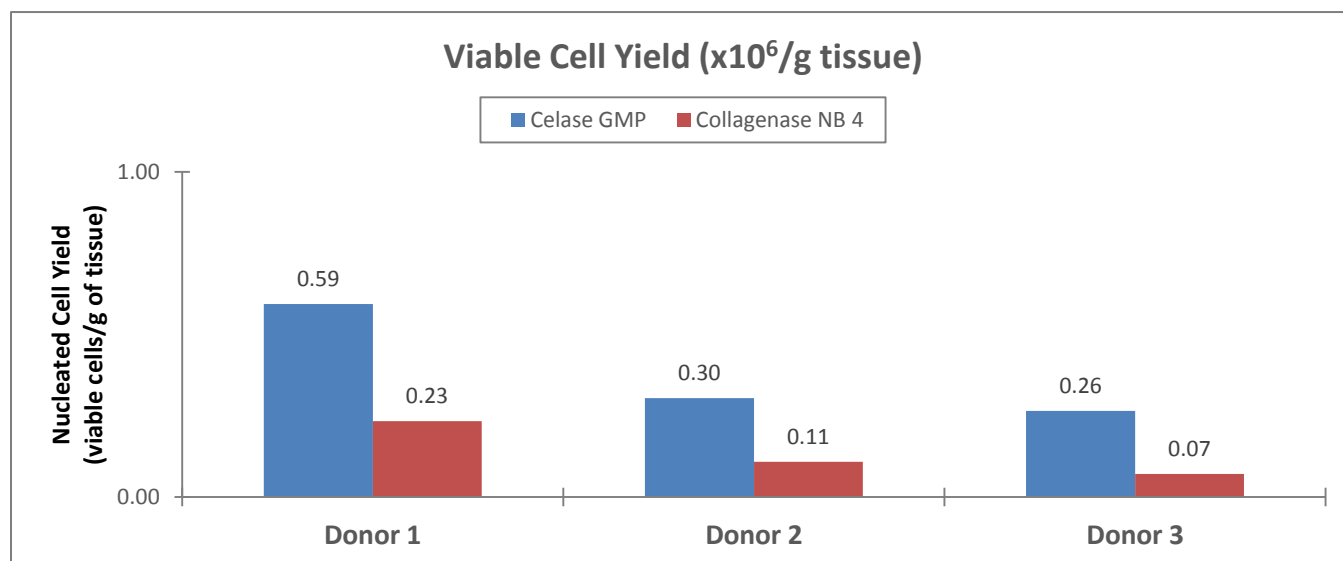


Figure 2. Viable cell yield from human lipoaspirate tissue with fixed collagenase concentration, digestion time, temperature and processing solution volume using tissue from three different donors. Celase GMP generated on average 3.0 times more nucleated cells from the same amount of the tissue. Data on file.

Cost Versus Cell Yield

When these data are combined with activity data:

	Cytori Celase GMP (35 mg pack)	SERVA Collagenase NB 6 GMP * (100 mg)
Avg Collagenase Activity (WU/mg), Fig 1	39.63	6.67
Avg Million Viable Cells/WU, Fig 2	0.387	0.137
WU/Million Viable Cells	2.58	7.28
mg Enzyme/Million Viable Cells **	0.07	1.09
Cost Per Vial	\$900	\$212***
Cost Per mg Enzyme	\$25.71	\$2.12
Cost Per 1 Million Viable Cells	\$1.68	\$2.32

* SERVA Collagenase NB4 and NB 6 have comparable enzymatic properties per the Collagenase NB brochure

** Viable cell yield may vary based on different donor tissue sample

*** Price for Collagenase NB 6 GMP in SERVA 2014 catalog; assumes \$1.10 = € 1.00

References

1. EnzChek Gelatinase Assay Kit IFU
2. Fraser JK, Zhu M, Wulur I, Alfonso Z. Adipose-derived stem cells. Methods Mol Biol. 2008; 449:59-67